Clinical trial results:
A PHASE 2, RANDOMIZED, DOUBLE-BLIND ASSESSMENT OF EFFICACY AND SAFETY OF PF-04171327 (1, 5, 10, 15 MG DOSE, DAILY) COMPARED TO 5 MG AND 10 MG PREDNISONE DAILY AND PLACEBO DAILY IN SUBJECTS WITH RHEUMATOID ARTHRITIS OVER AN 8 WEEK PERIOD FOLLOWED BY A 4 WEEK PERIOD OF TAPERING OF STUDY DRUG

Summary

EudraCT number	2010-023782-22
Trial protocol	ES CZ DE HU SK BG
Global end of trial date	09 June 2014

Results information

Result version number	v1 (current)
This version publication date	04 April 2016
First version publication date	06 July 2015

Trial information

Trial identification

Sponsor protocol code	A9391010

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01393639
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 East 42nd Street, New York, United States,
Public contact	Clinical Trials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Clinical Trials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 March 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 June 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare efficacy and safety of PF-04171327 (1, 5, 10 mg, 15 mg once daily) to 5 mg daily prednisone, 10 mg daily prednisone and placebo given over 8 weeks, in subjects with active rheumatoid arthritis (RA) on a stable background of methotrexate (MTX);

Determine comparative therapeutic window of PF 04171327 using American College of Rheumatology (ACR) 20 responses and change from baseline in procollagen type 1 N terminal propeptide (P1NP) and urinary N telopeptide (UNTx)/ urinary creatinine (uCr), (primary set of biomarkers) ie, determining a dose, or a range of doses, in which there is sufficient efficacy on the ACR20 and minor changes in P1NP and UNTx/uCr.

Protection of trial subjects:

The study was conducted in accordance with legal and regulatory requirements, as well as the general principles set forth in the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Council for International Organizations of Medical Sciences 2002), Guidelines for Good Clinical Practice (International Conference on Harmonization 1996), and the Declaration of Helsinki (World Medical Association 1996 and 2008).

An independent review committee (IRC) reviewed accumulating safety data from this study at 25%, 50%, 75% and 100% completion of study. The IRC members were independent of study team. Based on these reviews, the IRC had the capacity to make recommendations that might impact the conduct of the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 September 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Korea, Republic of: 18
Country: Number of subjects enrolled	Malaysia: 3
Country: Number of subjects enrolled	Mexico: 43
Country: Number of subjects enrolled	Romania: 8
Country: Number of subjects enrolled	Russian Federation: 92
Country: Number of subjects enrolled	Serbia: 4
Country: Number of subjects enrolled	Colombia: 15
Country: Number of subjects enrolled	United States: 16
Country: Number of subjects enrolled	Ukraine: 40

Country: Number of subjects enrolled	India: 4
Country: Number of subjects enrolled	Poland: 3
Country: Number of subjects enrolled	Slovakia: 23
Country: Number of subjects enrolled	Spain: 7
Country: Number of subjects enrolled	Bulgaria: 10
Country: Number of subjects enrolled	Czech Republic: 5
Country: Number of subjects enrolled	Germany: 4
Country: Number of subjects enrolled	Hungary: 28
Worldwide total number of subjects	323
EEA total number of subjects	88

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	260
From 65 to 84 years	63
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This multi-center, randomized, double-blind, parallel-group, active and placebo-controlled study randomized 323 participants in at 73 centers. An
additional 34 centers had no screening activities, but received study medication; and an additional 17 centers had at least 1 participant screened, but did
not randomize any participants.

Pre-assignment

Screening details:

Participants enrolled who had documented rheumatoid arthritis with a duration of at least 3 months as determined by the investigator using standardly
accepted criteria, had received methotrexate for at least 3 months to treat their rheumatoid arthritis, and were free of any signs or symptoms of infection.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

This study is participant-, investigator- and sponsor-blinded. At the initiation of the study, the study site was instructed on the method for blind-breaking. This method was to be an electronic process in order to maintain documentation and prevent accidental unblinding. Blinding codes were only to be broken in an emergency situation for reasons of participant safety.

Arms

Are arms mutually exclusive?	Yes
Arm title	PF-04171327 1 mg

Arm description:

Participants received PF-04171327 1 mg Once daily (QD) for 8 weeks. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.

Arm type	Experimental
Investigational medicinal product name	PF-04171327
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug.

Arm title	PF-04171327 5 mg

Arm description:

Participants received PF-04171327 5 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.

Arm type	Experimental

Investigational medicinal product name	PF-04171327
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

5 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug.

Arm title	PF-04171327 10 mg

Arm description:

Participants received PF-04171327 10 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.

Arm type	Experimental
Investigational medicinal product name	PF-04171327
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug.

Arm title	PF-04171327 15 mg

Arm description:

Participants received PF-04171327 15 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.

Arm type	Experimental
Investigational medicinal product name	PF-04171327
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

15 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug.

Arm title	Prednisone 5 mg

Arm description:

Participants received prednisone 5 mg QD for 8 weeks. From week 9 through 10, the participants received 1 prednisone 5 mg tablet + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 prednisone 5 mg capsule + 1 placebo tablet every 3 days.

Arm type	Active comparator
Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

5 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off prednisone.

Arm title	Prednisone 10 mg

Arm description:

Participants received prednisone 10 mg QD for 8 weeks. After 8 weeks of treatment, participants were tapered off prednisone dosage. From week 9 through 10, the participants received 1 prednisone 5 mg tablet + 1 placebo tablet every other day. From week 11 through 12, the participants received 1

prednisone 5 mg tablet + 1 placebo tablet every 3 days.

Arm type	Active comparator
Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

10 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off prednisone.

Arm title	Placebo

Arm description:

Participants received 2 tablets of placebo QD every other day at weeks 9 and 10 dosing and every 3 days at weeks 11 and 12 dosing.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo QD until week 12.

Number of subjects in period 1	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg
Started	45	47	45
Completed	42	40	44
Not completed	3	7	1
Consent withdrawn by subject	1	1	-
Adverse Event	2	3	1
Not specified	-	2	-
Protocol Violation	-	-	-
Medication error without associated AE	-	-	-
Lost to follow-up	-	1	-
Lack of efficacy	-	-	-

Number of subjects in period 1	PF-04171327 15 mg	Prednisone 5 mg	Prednisone 10 mg
Started	48	45	46
Completed	43	44	44
Not completed	5	1	2
Consent withdrawn by subject	-	-	-
Adverse Event	2	-	2
Not specified	2	1	-
Protocol Violation	1	-	-
Medication error without associated AE	-	-	-

Lost to follow-up	-	-	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Placebo
Started	47
Completed	39
Not completed	8
Consent withdrawn by subject	1
Adverse Event	3
Not specified	1
Protocol Violation	-
Medication error without associated AE	1
Lost to follow-up	1
Lack of efficacy	1

Baseline characteristics

Reporting groups	
Reporting group title	PF-04171327 1 mg
Reporting group description:	
Participants received PF-04171327 1 mg Once daily (QD) for 8 weeks. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.	
Reporting group title	PF-04171327 5 mg
Reporting group description:	
Participants received PF-04171327 5 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.	
Reporting group title	PF-04171327 10 mg
Reporting group description:	
Participants received PF-04171327 10 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.	
Reporting group title	PF-04171327 15 mg
Reporting group description:	
Participants received PF-04171327 15 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.	
Reporting group title	Prednisone 5 mg
Reporting group description:	
Participants received prednisone 5 mg QD for 8 weeks. From week 9 through 10, the participants received 1 prednisone 5 mg tablet + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 prednisone 5 mg capsule + 1 placebo tablet every 3 days.	
Reporting group title	Prednisone 10 mg
Reporting group description:	
Participants received prednisone 10 mg QD for 8 weeks. After 8 weeks of treatment, participants were tapered off prednisone dosage. From week 9 through 10, the participants received 1 prednisone 5 mg tablet + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 prednisone 5 mg tablet + 1 placebo tablet every 3 days.	
Reporting group title	Placebo
Reporting group description:	
Participants received 2 tablets of placebo QD every other day at weeks 9 and 10 dosing and every 3 days at weeks 11 and 12 dosing.	

Reporting group values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg
Number of subjects	45	47	45
Age categorical Units: Subjects			
Adults (18-64 years)	40	36	33
From 65-84 years	5	11	12
Age continuous Units: years			
arithmetic mean	50.4	55.1	54.7
standard deviation	± 14.2	± 12.1	± 13.1

Gender categorical Units: Subjects			
Female	33	38	34
Male	12	9	11

Reporting group values	PF-04171327 15 mg	Prednisone 5 mg	Prednisone 10 mg
Number of subjects	48	45	46
Age categorical Units: Subjects			
Adults (18-64 years)	43	38	33
From 65-84 years	5	7	13
Age continuous Units: years			
arithmetic mean	54	52.9	57.3
standard deviation	± 11.1	± 11.2	± 10.7
Gender categorical Units: Subjects			
Female	37	39	41
Male	11	6	5

Reporting group values	Placebo	Total	
Number of subjects	47	323	
Age categorical Units: Subjects			
Adults (18-64 years)	37	260	
From 65-84 years	10	63	
Age continuous Units: years			
arithmetic mean	55.2		
standard deviation	± 13.2	-	
Gender categorical Units: Subjects			
Female	37	259	
Male	10	64	

End points reporting groups

Reporting group title	PF-04171327 1 mg
Reporting group description:	
Participants received PF-04171327 1 mg Once daily (QD) for 8 weeks. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.	
Reporting group title	PF-04171327 5 mg
Reporting group description:	
Participants received PF-04171327 5 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.	
Reporting group title	PF-04171327 10 mg
Reporting group description:	
Participants received PF-04171327 10 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.	
Reporting group title	PF-04171327 15 mg
Reporting group description:	
Participants received PF-04171327 15 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.	
Reporting group title	Prednisone 5 mg
Reporting group description:	
Participants received prednisone 5 mg QD for 8 weeks. From week 9 through 10, the participants received 1 prednisone 5 mg tablet + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 prednisone 5 mg capsule + 1 placebo tablet every 3 days.	
Reporting group title	Prednisone 10 mg
Reporting group description:	
Participants received prednisone 10 mg QD for 8 weeks. After 8 weeks of treatment, participants were tapered off prednisone dosage. From week 9 through 10, the participants received 1 prednisone 5 mg tablet + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 prednisone 5 mg tablet + 1 placebo tablet every 3 days.	
Reporting group title	Placebo
Reporting group description:	
Participants received 2 tablets of placebo QD every other day at weeks 9 and 10 dosing and every 3 days at weeks 11 and 12 dosing.	

Primary: Proportion of participants achieving a 20% improvement in American College of Rheumatology (ACR) criteria at Week 8

End point title	Proportion of participants achieving a 20% improvement in American College of Rheumatology (ACR) criteria at Week 8

End point description:

ACR20 response: greater than or equal to (≥) 20 percent (%) improvement in tender joint count; ≥ 20% improvement in swollen joint count; and ≥ 20% improvement in at least 3 of 5 remaining ACR core measures: participant assessment of pain; participant global assessment of disease activity; physician global assessment of disease activity; self-assessed disability (disability index of the Health Assessment Questionnaire [HAQ]); and C-Reactive Protein (CRP).

Full Analysis Set (FAS) used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF-04171327, prednisone, or placebo).

End point type	Primary

End point timeframe:

Week 8

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	45	48
Units: Percentage of participants	47	61	69	73

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	46	47	
Units: Percentage of participants	51	71	37	

Statistical analyses

Statistical analysis title	1. ACR20 response rates at Week 8

Statistical analysis description:

Week 8 is the primary timepoint of interest. Bayesian 4 Parameter Emax Model Based Estimates are provided. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group. The total number of subjects used in fitting the Bayesian Emax model is the total number of subjects in the FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other[1]
Parameter estimate	Difference in proportions
Point estimate	10
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	5
upper limit	15

Notes:

[1] - Superiority criterion versus placebo: Lower bound of 60% credible interval >20%. Non-responder imputation was used to handle dropouts at Week 8.

Statistical analysis title	2. ACR20 response rates at Week 8

Statistical analysis description:

Week 8 is the primary timepoint of interest. Bayesian 4 Parameter Emax Model Based Estimates are provided. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group. The total number of subjects used in fitting the Bayesian Emax model is the total number of subjects in the FAS.

Comparison groups	PF-04171327 5 mg v Placebo

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other[2]
Parameter estimate	Difference in proportions
Point estimate	24
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	18
upper limit	31

Notes:

[2] - Superiority criterion versus placebo: Lower bound of 60% credible interval >20%. Non-responder imputation was used to handle dropouts at Week 8.

Statistical analysis title	3. ACR20 response rates at Week 8

Statistical analysis description:

Week 8 is the primary timepoint of interest. Bayesian 4 Parameter Emax Model Based Estimates are provided. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group. The total number of subjects used in fitting the Bayesian Emax model is the total number of subjects in the FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other[3]
Parameter estimate	Difference in proportions
Point estimate	32
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	25
upper limit	39

Notes:

[3] - Superiority criterion versus placebo: Lower bound of 60% credible interval >20%. Non-responder imputation was used to handle dropouts at Week 8.

Statistical analysis title	4. ACR20 response rates at Week 8

Statistical analysis description:

Week 8 is the primary timepoint of interest. Bayesian 4 Parameter Emax Model Based Estimates are provided. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group. The total number of subjects used in fitting the Bayesian Emax model is the total number of subjects in the FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other[4]
Parameter estimate	Difference in proportions
Point estimate	36
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	29
upper limit	43

Notes:

[4] - Superiority criterion versus placebo: Lower bound of 60% credible interval >20%. Non-responder imputation was used to handle dropouts at Week 8.

Statistical analysis title	5. ACR20 response rates at Week 8

Statistical analysis description:

Week 8 is the primary timepoint of interest. Bayesian 4 Parameter Emax Model Based Estimates are provided. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group. The total number of subjects used in fitting the Bayesian Emax model is the total number of subjects in the FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other[5]
Parameter estimate	Difference in proportions
Point estimate	14
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	6
upper limit	22

Notes:

[5] - Superiority criterion versus placebo: Lower bound of 60% credible interval >20%. Non-responder imputation was used to handle dropouts at Week 8.

Statistical analysis title	6. ACR20 response rates at Week 8

Statistical analysis description:

Week 8 is the primary timepoint of interest. Bayesian 4 Parameter Emax Model Based Estimates are provided. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group. The total number of subjects used in fitting the Bayesian Emax model is the total number of subjects in the FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other[6]
Parameter estimate	Difference in proportions
Point estimate	34
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	27
upper limit	42

Notes:

[6] - Superiority criterion versus placebo: Lower bound of 60% credible interval >20%. Non-responder imputation was used to handle dropouts at Week 8.

Statistical analysis title	7. ACR20 response rates at Week 8

Statistical analysis description:

Week 8 is the primary timepoint of interest. Bayesian 4 Parameter Emax Model Based Estimates are provided. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group. The total number of subjects used in fitting the Bayesian Emax model is the total number of subjects in the FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other[7]
Parameter estimate	Difference in proportions
Point estimate	-24
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-32
upper limit	-17

Notes:

[7] - Superiority criterion versus placebo: Lower bound of 60% credible interval >20%. Non-responder imputation was used to handle dropouts at Week 8.

Statistical analysis title	8. ACR20 response rates at Week 8

Statistical analysis description:

Week 8 is the primary timepoint of interest. Bayesian 4 Parameter Emax Model Based Estimates are provided. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group. The total number of subjects used in fitting the Bayesian Emax model is the total number of subjects in the FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other[8]
Parameter estimate	Difference in proportions
Point estimate	-10
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-16
upper limit	-4

Notes:

[8] - Superiority criterion versus placebo: Lower bound of 60% credible interval >20%. Non-responder imputation was used to handle dropouts at Week 8.

Statistical analysis title	9. ACR20 response rates at Week 8

Statistical analysis description:

Week 8 is the primary timepoint of interest. Bayesian 4 Parameter Emax Model Based Estimates are provided.The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group. The total number of subjects used in fitting the Bayesian Emax model is the total number of subjects in the FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other[9]
Parameter estimate	Difference in proportions
Point estimate	-2
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-9
upper limit	4

Notes:

[9] - Superiority criterion versus placebo: Lower bound of 60% credible interval >20%. Non-responder imputation was used to handle dropouts at Week 8.

Statistical analysis title	10. ACR20 response rates at Week 8

Statistical analysis description:

Week 8 is the primary timepoint of interest. Bayesian 4 Parameter Emax Model Based Estimates are provided. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group. The total number of subjects used in fitting the Bayesian Emax model is the total number of subjects in the FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other[10]
Parameter estimate	Difference in proportions
Point estimate	1
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-5
upper limit	8

Notes:

[10] - Superiority criterion versus placebo: Lower bound of 60% credible interval >20%. Non-responder imputation was used to handle dropouts at Week 8.

Primary: Percent change from Baseline 0 hour in procollagen type 1 N terminal propeptide (P1NP) at Week 8, 0 hour (comparisons to Prednisone 5 mg)

End point title	Percent change from Baseline 0 hour in procollagen type 1 N terminal propeptide (P1NP) at Week 8, 0 hour (comparisons to Prednisone 5 mg)

End point description:

Change from baseline in P1NP at week 8 is presented.
FAS used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo).

End point type	Primary

End point timeframe:

Week 8

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	42	44	43
Units: NG/ML				
least squares mean (standard error)	-3.25 (± 5.5)	-11.6 (± 5.55)	-9.96 (± 5.49)	-16.63 (± 5.55)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	43	44	41	

Units: NG/ML				
least squares mean (standard error)	-4.89 (± 5.55)	-20.14 (± 5.5)	14.19 (± 5.56)	

Statistical analyses

Statistical analysis title	1. P1NP at Week 8 (primary timepoint of interest)

Statistical analysis description:

Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in the FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 5 mg
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.75
upper limit	17.03

Statistical analysis title	2. P1NP at Week 8 (primary timepoint of interest)

Statistical analysis description:

Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in the FAS.

Comparison groups	Prednisone 5 mg v PF-04171327 5 mg
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-6.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.16
upper limit	8.75

Statistical analysis title	3. P1NP at Week 8 (primary timepoint of interest)

Statistical analysis description:

Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in the FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 5 mg
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-5.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.45
upper limit	10.3

Statistical analysis title	4. P1NP at Week 8 (primary timepoint of interest)

Statistical analysis description:

Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in the FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 5 mg
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-11.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.19
upper limit	3.72

Primary: Percent change from Baseline 0 hour in urinary N telopeptide/urinary creatinine (uNTx/uCr) at Week 8, 0 hour (comparisons to Prednisone 5 mg)

End point title	Percent change from Baseline 0 hour in urinary N telopeptide/urinary creatinine (uNTx/uCr) at Week 8, 0 hour (comparisons to Prednisone 5 mg)

End point description:

Change from baseline in uNTx/uCr at week 8 is presented.
FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo).

End point type	Primary

End point timeframe:

Week 8

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	42	43	43
Units: nM BCE/mM				
least squares mean (standard error)	6.08 (± 5.83)	-3.78 (± 5.88)	6.96 (± 5.86)	15.57 (± 5.83)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	43	43	42	
Units: nM BCE/mM				
least squares mean (standard error)	2.74 (± 5.87)	-9.14 (± 5.83)	3.81 (± 5.88)	

Statistical analyses

Statistical analysis title	uNTx/uCr at Week 8 (primary timepoint of interest)

Statistical analysis description:

Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field ‘number of subjects included in analysis’ displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in the FAS.

Comparison groups	Prednisone 5 mg v PF-04171327 1 mg
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	3.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.92
upper limit	19.61

Statistical analysis title	uNTx/uCr at Week 8 (primary timepoint of interest)

Statistical analysis description:

Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field ‘number of subjects included in analysis’ displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in the FAS.

Comparison groups	Prednisone 5 mg v PF-04171327 5 mg

Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-6.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.86
upper limit	9.81

Statistical analysis title	uNTx/uCr at Week 8 (primary timepoint of interest)

Statistical analysis description:

Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'number of subjects included in analysis' displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in the FAS.

Comparison groups	Prednisone 5 mg v PF-04171327 10 mg
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	4.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.11
upper limit	20.55

Statistical analysis title	uNTx/uCr at Week 8 (primary timepoint of interest)

Statistical analysis description:

Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'number of subjects included in analysis' displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in the FAS.

Comparison groups	Prednisone 5 mg v PF-04171327 15 mg
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	12.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.49
upper limit	29.15

Secondary: ACR20 response rate at Weeks 2, 4, and 12 (comparisons to placebo, and prednisone 10 mg)

End point title	ACR20 response rate at Weeks 2, 4, and 12 (comparisons to placebo, and prednisone 10 mg)

End point description:

ACR20 response: 20% improvement in tender and swollen joint counts and 20% improvement in 3 of the 5 remaining ACR-core set measures: participant and physician global assessments, pain, disability, and an acute phase reactant.

FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo). Note: In the table below, n=number of ACR20 responders in the PF-04171327 1mg, 5mg, 10mg, 15mg, Prednisone 5mg and 10mg, and placebo groups respectively.

In the table below, the values provided for the field "arithmetic mean" represent proportion of responders.

End point type	Secondary

End point timeframe:

Weeks 2, 4, and 12 (taper period)

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	45	48
Units: Response Rate				
arithmetic mean (standard error)				
Week 2 (n=14, 15, 18, 20, 13, 17, 9)	31.82 (± 7.02)	32.61 (± 6.91)	40 (± 7.3)	42.55 (± 7.21)
Week 4 (n=14, 26, 30, 25, 22, 30, 18)	31.11 (± 6.9)	55.32 (± 7.25)	66.67 (± 7.02)	53.19 (± 7.27)
Week 12 (n=16, 23, 25, 18, 22, 26, 15)	35.56 (± 7.13)	48.94 (± 7.29)	55.56 (± 7.4)	38.3 (± 7.09)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	46	47	
Units: Response Rate				
arithmetic mean (standard error)				
Week 2 (n=14, 15, 18, 20, 13, 17, 9)	28.89 (± 6.75)	36.96 (± 7.11)	20.45 (± 6.08)	
Week 4 (n=14, 26, 30, 25, 22, 30, 18)	48.89 (± 7.45)	65.22 (± 7.02)	40 (± 7.3)	
Week 12 (n=16, 23, 25, 18, 22, 26, 15)	48.89 (± 7.45)	56.52 (± 7.3)	33.33 (± 7.02)	

Statistical analyses

Statistical analysis title	1. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	11.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.84
upper limit	29.56

Statistical analysis title	2. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	12.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.88
upper limit	30.19

Statistical analysis title	3. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	19.54

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	38.17

Statistical analysis title	4. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	22.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.6
upper limit	40.58

Statistical analysis title	5. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	8.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.38
upper limit	26.25

Statistical analysis title	6. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	16.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.84
upper limit	34.84

Statistical analysis title	7. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-8.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.58
upper limit	10.8

Statistical analysis title	8. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	15.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.85
upper limit	35.49

Statistical analysis title	9. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	26.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.8
upper limit	46.53

Statistical analysis title	10. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	13.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.01
upper limit	33.4

Statistical analysis title	11. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 5 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	8.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.56
upper limit	29.33

Statistical analysis title	12. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	25.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.35
upper limit	45.07

Statistical analysis title	13. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 12 (taper period) results presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	2.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.4
upper limit	21.85

Statistical analysis title	14. ACR20 response rate at Weeks 2, 4, and 12
Statistical analysis description:	
Week 12 (taper period) results presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.	
Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	15.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.24
upper limit	35.45

Statistical analysis title	15. ACR20 response rate at Weeks 2, 4, and 12
Statistical analysis description:	
Week 12 (taper period) results presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.	
Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	22.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.2
upper limit	42.23

Statistical analysis title	16. ACR20 response rate at Weeks 2, 4, and 12
Statistical analysis description:	
Week 12 (taper period) results presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.	
Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	4.96

Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.6
upper limit	24.53

Statistical analysis title	17. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 12 (taper period) results presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	15.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.51
upper limit	35.63

Statistical analysis title	18. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 12 (taper period) results presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	23.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.31
upper limit	43.06

Statistical analysis title	19. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-5.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.73
upper limit	14.45

Statistical analysis title	20. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-4.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.79
upper limit	15.09

Statistical analysis title	21. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	3.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.94
upper limit	23.02

Statistical analysis title	22. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	5.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.26
upper limit	25.45

Statistical analysis title	23. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-34.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-53.4
upper limit	-14.8

Statistical analysis title	24. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-9.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.68
upper limit	9.88

Statistical analysis title	25. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	1.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.02
upper limit	20.92

Statistical analysis title	26. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-12.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.84
upper limit	7.79

Statistical analysis title	27. ACR20 response rate at Weeks 2, 4, and 12
Statistical analysis description:	
Week 12 (taper period) results presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.	
Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-20.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-40.98
upper limit	-0.94

Statistical analysis title	28. ACR20 response rate at Weeks 2, 4, and 12
Statistical analysis description:	
Week 12 (taper period) results presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.	
Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-7.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.82
upper limit	12.65

Statistical analysis title	29. ACR20 response rate at Weeks 2, 4, and 12
Statistical analysis description:	
Week 12 (taper period) results presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.	
Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-0.96

Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.36
upper limit	19.43

Statistical analysis title	30. ACR20 response rate at Weeks 2, 4, and 12

Statistical analysis description:

Week 12 (taper period) results presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR20 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-18.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-38.18
upper limit	1.73

Secondary: ACR50 response rate at Weeks 2, 4, 6, 8 and 12 (comparisons to placebo, and prednisone 10 mg)

End point title	ACR50 response rate at Weeks 2, 4, 6, 8 and 12 (comparisons to placebo, and prednisone 10 mg)

End point description:

ACR50 response: greater than or equal to (≥) 50 percent (%) improvement in tender or swollen joint counts and 50% improvement in 3 of the following 5 criteria: 1) physician's global assessment of disease activity, 2) participant's assessment of disease activity, 3) participant's assessment of pain, 4) participant's assessment of functional disability via a health assessment questionnaire, and 5) C-reactive protein at each visit.
FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo).
Note: In the table below, n=number of ACR50 responders in the PF-04171327 1mg, 5mg, 10mg, 15mg, Prednisone 5mg and 10mg, and placebo groups respectively.
In the table below, the values provided for the field "arithmetic mean" represent proportion of responders.

End point type	Secondary

End point timeframe:

Weeks 2, 4, 6, 8, and 12 (taper period)

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	45	48
Units: Response Rate				
arithmetic mean (standard error)				
Week 2 (n=2, 4, 4, 12, 1, 9, 3)	4.55 (± 3.14)	8.7 (± 4.15)	8.89 (± 4.24)	25.53 (± 6.36)
Week 4 (n=4, 11, 16, 13, 5, 14, 5)	8.89 (± 4.24)	23.4 (± 6.17)	35.56 (± 7.13)	27.66 (± 6.52)
Week 6 (n=5, 13, 18, 20, 11, 17, 7)	11.11 (± 4.68)	27.66 (± 6.52)	40 (± 7.3)	42.55 (± 7.21)
Week 8 (n=10, 15, 22, 20, 12, 21, 6)	22.22 (± 6.19)	31.91 (± 6.79)	48.89 (± 7.45)	42.55 (± 7.21)
Week 12 (n=8, 10, 11, 8, 12, 11, 8)	17.78 (± 5.69)	21.28 (± 5.96)	24.44 (± 6.4)	17.02 (± 5.48)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	46	47	
Units: Response Rate				
arithmetic mean (standard error)				
Week 2 (n=2, 4, 4, 12, 1, 9, 3)	2.22 (± 2.19)	19.57 (± 5.84)	6.82 (± 3.79)	
Week 4 (n=4, 11, 16, 13, 5, 14, 5)	11.11 (± 4.68)	30.43 (± 6.78)	11.11 (± 4.68)	
Week 6 (n=5, 13, 18, 20, 11, 17, 7)	24.44 (± 6.4)	36.96 (± 7.11)	15.56 (± 5.4)	
Week 8 (n=10, 15, 22, 20, 12, 21, 6)	26.67 (± 6.59)	45.65 (± 7.34)	13.33 (± 5.06)	
Week 12 (n=8, 10, 11, 8, 12, 11, 8)	26.67 (± 6.59)	23.91 (± 6.28)	17.78 (± 5.69)	

Statistical analyses

Statistical analysis title	1. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-2.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.93
upper limit	7.38

Statistical analysis title	2. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Placebo v PF-04171327 10 mg
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	2.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.09
upper limit	13.23

Statistical analysis title	3. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	18.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.19
upper limit	33.23

Statistical analysis title	4. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-4.59

Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.19
upper limit	4

Statistical analysis title	5. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	12.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.92
upper limit	26.41

Statistical analysis title	6. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-2.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.6
upper limit	10.16

Statistical analysis title	7. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	12.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	27.48

Statistical analysis title	8. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	24.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.71
upper limit	41.17

Statistical analysis title	9. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.98
upper limit	12.98

Statistical analysis title	10. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	19.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.16
upper limit	35.48

Statistical analysis title	11. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-4.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.46
upper limit	9.57

Statistical analysis title	12. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Placebo

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	12.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.49
upper limit	28.7

Statistical analysis title	13. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	24.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.63
upper limit	42.24

Statistical analysis title	14. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	26.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.33
upper limit	44.65

Statistical analysis title	15. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	8.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.53
upper limit	25.31

Statistical analysis title	16. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	21.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.88
upper limit	38.91

Statistical analysis title	17. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	8.88

Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8
upper limit	24.57

Statistical analysis title	18. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	18.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.96
upper limit	35.2

Statistical analysis title	19. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	35.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.89
upper limit	53.21

Statistical analysis title	20. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point

estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	29.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.94
upper limit	46.49

Statistical analysis title	21. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	13.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.96
upper limit	29.63

Statistical analysis title	22. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	32.31

Confidence interval	
level	95 %
sides	2-sided
lower limit	14.83
upper limit	49.8

Statistical analysis title	23. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.79
upper limit	15.79

Statistical analysis title	24. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	3.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.67
upper limit	19.67

Statistical analysis title	25. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	6.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.13
upper limit	23.47

Statistical analysis title	26. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.25
upper limit	14.74

Statistical analysis title	27. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	8.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.19
upper limit	25.96

Statistical analysis title	28. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	6.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.5
upper limit	22.77

Statistical analysis title	29. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-15.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.03
upper limit	-2

Statistical analysis title	30. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-10.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.93
upper limit	3.19

Statistical analysis title	31. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-10.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.83
upper limit	3.48

Statistical analysis title	32. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	5.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.96
upper limit	22.9

Statistical analysis title	33. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-21.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	-37.22
upper limit	-5.86

Statistical analysis title	34. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-7.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.01
upper limit	10.95

Statistical analysis title	35. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	5.12

Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.17
upper limit	24.41

Statistical analysis title	36. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-2.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.22
upper limit	15.67

Statistical analysis title	37. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-25.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	-42.54
upper limit	-9.14

Statistical analysis title	38. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-9.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.22
upper limit	9.62

Statistical analysis title	39. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	3.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.94
upper limit	23.02

Statistical analysis title	40. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	5.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.26
upper limit	25.45

Statistical analysis title	41. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-23.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-42.26
upper limit	-4.59

Statistical analysis title	42. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-13.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.35
upper limit	5.87

Statistical analysis title	43. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	3.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.26
upper limit	23.74

Statistical analysis title	44. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-3.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.27
upper limit	17.07

Statistical analysis title	45. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-6.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.77
upper limit	10.5

Statistical analysis title	46. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-2.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.63
upper limit	14.35

Statistical analysis title	47. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.06
upper limit	18.12

Statistical analysis title	48. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-6.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.24
upper limit	9.46

Statistical analysis title	49. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	1.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.15
upper limit	12.91

Statistical analysis title	50. ACR50 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR50 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	16.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	32.29

Secondary: ACR70 response rate at Weeks 2, 4, 6, 8 and 12 (comparisons to placebo, and prednisone 10 mg)

End point title	ACR70 response rate at Weeks 2, 4, 6, 8 and 12 (comparisons to placebo, and prednisone 10 mg)

End point description:

ACR70 response: ≥ 70% improvement in tender or swollen joint counts and 70% improvement in 3 of following 5 criteria: participant and physician global assessments, pain, disability, and an acute phase reactant.
FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo).
Note: In the table below, n=number of ACR70 responders in the PF-04171327 1mg, 5mg, 10mg, 15mg, Prednisone 5mg and 10mg, and placebo groups respectively.
In the table below, the values provided for the field "arithmetic mean" represent proportion of responders.

End point type	Secondary

End point timeframe:

Weeks 2, 4, 6, 8, and 12 (taper period)

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	45	48
Units: Response Rate				
arithmetic mean (standard error)				
Week 2 (n=0, 2, 1, 3, 1, 4, 0)	0 (± 0)	4.35 (± 3)	2.22 (± 2.19)	6.38 (± 3.56)
Week 4 (n=0, 4, 7, 8, 2, 7, 0)	0 (± 0)	8.51 (± 4.07)	15.56 (± 5.4)	17.02 (± 5.48)
Week 6 (n=1, 6, 6, 8, 3, 10, 2)	2.22 (± 2.19)	12.77 (± 4.86)	13.33 (± 5.06)	17.02 (± 5.48)
Week 8 (4, 8, 12, 10, 3, 12, 5)	8.89 (± 4.24)	17.02 (± 5.48)	26.67 (± 6.59)	21.28 (± 5.96)
Week 12 (n=3, 6, 3, 4, 5, 5 ,3)	6.67 (± 3.71)	12.77 (± 4.86)	6.67 (± 3.71)	8.51 (± 4.07)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	46	47	
Units: Response Rate				
arithmetic mean (standard error)				
Week 2 (n=0, 2, 1, 3, 1, 4, 0)	2.22 (± 2.19)	8.7 (± 4.15)	0 (± 0)	
Week 4 (n=0, 4, 7, 8, 2, 7, 0)	4.44 (± 3.07)	15.22 (± 5.29)	0 (± 0)	
Week 6 (n=1, 6, 6, 8, 3, 10, 2)	6.67 (± 3.71)	21.74 (± 6.08)	4.44 (± 3.07)	
Week 8 (4, 8, 12, 10, 3, 12, 5)	6.67 (± 3.71)	26.09 (± 6.47)	11.11 (± 4.68)	
Week 12 (n=3, 6, 3, 4, 5, 5 ,3)	11.11 (± 4.68)	10.87 (± 4.58)	6.67 (± 3.71)	

Statistical analyses

Statistical analysis title	1. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	2. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	4.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.54
upper limit	10.24

Statistical analysis title	3. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	2.22

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.08
upper limit	6.52

Statistical analysis title	4. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	6.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.6
upper limit	13.37

Statistical analysis title	5. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for binomial proportions, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	2.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.08
upper limit	6.52

Statistical analysis title	6. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	8.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	16.83

Statistical analysis title	7. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	8. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	8.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	16.48

Statistical analysis title	9. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	15.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.96
upper limit	26.14

Statistical analysis title	10. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	17.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.27
upper limit	27.76

Statistical analysis title	11. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 5 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	4.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.57
upper limit	10.46

Statistical analysis title	12. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	15.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.83
upper limit	25.59

Statistical analysis title	13. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-2.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.62
upper limit	5.18

Statistical analysis title	14. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	8.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.96
upper limit	19.6

Statistical analysis title	15. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	8.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.72
upper limit	20.5

Statistical analysis title	16. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	12.57

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.26
upper limit	24.89

Statistical analysis title	17. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	2.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.23
upper limit	11.67

Statistical analysis title	18. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	17.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.94
upper limit	30.64

Statistical analysis title	19. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-2.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.6
upper limit	10.16

Statistical analysis title	20. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	5.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.22
upper limit	20.04

Statistical analysis title	21. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	15.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.29
upper limit	31.4

Statistical analysis title	22. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	10.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.7
upper limit	25.03

Statistical analysis title	23. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-4.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.16
upper limit	7.27

Statistical analysis title	24. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 10 mg v Placebo

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	14.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.68
upper limit	30.63

Statistical analysis title	25. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.3
upper limit	10.3

Statistical analysis title	26. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	6.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.9
upper limit	18.1

Statistical analysis title	27. ACR70 response rate at Weeks 2, 4, 6, 8 and 12
Statistical analysis description:	
Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.	
Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.3
upper limit	10.3

Statistical analysis title	28. ACR70 response rate at Weeks 2, 4, 6, 8 and 12
Statistical analysis description:	
Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.	
Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	1.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.96
upper limit	12.64

Statistical analysis title	29. ACR70 response rate at Weeks 2, 4, 6, 8 and 12
Statistical analysis description:	
Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.	
Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	4.44

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.27
upper limit	16.16

Statistical analysis title	30. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	4.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.37
upper limit	15.77

Statistical analysis title	31. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-8.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.83
upper limit	-0.55

Statistical analysis title	32. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-4.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.39
upper limit	5.7

Statistical analysis title	33. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-6.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.68
upper limit	2.73

Statistical analysis title	34. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 2 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-2.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.04
upper limit	8.41

Statistical analysis title	35. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-15.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.59
upper limit	-4.83

Statistical analysis title	36. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-6.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.79
upper limit	6.38

Statistical analysis title	37. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.49
upper limit	15.16

Statistical analysis title	38. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 4 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.13
upper limit	16.74

Statistical analysis title	39. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-19.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.19
upper limit	-6.84

Statistical analysis title	40. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	Prednisone 10 mg v PF-04171327 5 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-8.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.24
upper limit	6.29

Statistical analysis title	41. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-8.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.92
upper limit	7.1

Statistical analysis title	42. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 6 analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-4.71

Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.76
upper limit	11.32

Statistical analysis title	43. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-17.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.36
upper limit	-2.02

Statistical analysis title	44. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-9.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.69
upper limit	7.56

Statistical analysis title	45. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point

estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	0.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.53
upper limit	18.68

Statistical analysis title	46. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 8 (primary timepoint of interest) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-4.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.07
upper limit	12.45

Statistical analysis title	47. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-4.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.77
upper limit	7.37

Statistical analysis title	48. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	1.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.21
upper limit	15

Statistical analysis title	49. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-4.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.77
upper limit	7.37

Statistical analysis title	50. ACR70 response rate at Weeks 2, 4, 6, 8 and 12

Statistical analysis description:

Week 12 (taper period) analysis presented. Non-responder imputation was used to handle dropouts. Analyzed using normal approximation for difference in binomial proportions. Point estimates for ACR70 response rate, treatment differences and CIs for treatment differences were reported by week.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in proportions
Point estimate	-2.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.38
upper limit	9.66

Secondary: Change from Baseline in Tender-Joint Counts at Weeks 2, 4, 6, 8 (comparisons to placebo, and prednisone 10 mg)

End point title	Change from Baseline in Tender-Joint Counts at Weeks 2, 4, 6, 8 (comparisons to placebo, and prednisone 10 mg)

End point description:

Twenty-eight tender/painful joint count included the following joints: shoulders, elbows, wrists, metacarpophalangeal joints, proximal interphalangeal joints, and knees. Artificial joints were not assessed. These joints were assessed by a joint assessor, who was blinded to the participant's safety data, previous efficacy data and treatment randomization, to determine the number of joints that were considered tender or painful, and swollen.

FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Weeks 2, 4, 6, and 8

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	45	48
Units: Joints				
least squares mean (standard error)				
Week 2	-4.08 (± 0.74)	-5.55 (± 0.72)	-4.97 (± 0.73)	-5.65 (± 0.72)
Week 4	-5.97 (± 0.8)	-6.99 (± 0.79)	-7.01 (± 0.8)	-6.93 (± 0.79)
Week 6	-6.87 (± 0.87)	-8.83 (± 0.87)	-8.37 (± 0.87)	-8.31 (± 0.86)
Week 8	-7.06 (± 0.91)	-8.65 (± 0.92)	-9.46 (± 0.91)	-9.17 (± 0.91)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	46	47	
Units: Joints				
least squares mean (standard error)				
Week 2	-3.88 (± 0.73)	-5.38 (± 0.72)	-1.95 (± 0.74)	
Week 4	-5.79 (± 0.8)	-7.44 (± 0.79)	-4.16 (± 0.8)	

Week 6	-6.91 (± 0.87)	-8.75 (± 0.86)	-4.64 (± 0.87)	
Week 8	-7 (± 0.91)	-8.84 (± 0.9)	-4.27 (± 0.92)	

Statistical analyses

Statistical analysis title	1. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.19
upper limit	-0.07

Statistical analysis title	2. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.63
upper limit	-1.57

Statistical analysis title	3. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.06
upper limit	-0.97

Statistical analysis title	4. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.73
upper limit	-1.68

Statistical analysis title	5. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.97
upper limit	0.12

Statistical analysis title	6. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.46
upper limit	-1.39

Statistical analysis title	7. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.03
upper limit	0.42

Statistical analysis title	8. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.04
upper limit	-0.62

Statistical analysis title	9. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.07
upper limit	-0.64

Statistical analysis title	10. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo

Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.98
upper limit	-0.56

Statistical analysis title	11. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.85
upper limit	0.59

Statistical analysis title	12. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.48
upper limit	-1.06

Statistical analysis title	13. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.66
upper limit	0.2

Statistical analysis title	14. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-4.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.62
upper limit	-1.77

Statistical analysis title	15. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.15
upper limit	-1.31

Statistical analysis title	16. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.09
upper limit	-1.26

Statistical analysis title	17. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.69
upper limit	0.16

Statistical analysis title	18. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-4.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.52
upper limit	-1.7

Statistical analysis title	19. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.34
upper limit	-0.25

Statistical analysis title	20. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Placebo

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-4.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.93
upper limit	-1.83

Statistical analysis title	21. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-5.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.74
upper limit	-2.66

Statistical analysis title	22. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-4.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.43
upper limit	-2.36

Statistical analysis title	23. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.28
upper limit	-0.2

Statistical analysis title	24. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-4.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	-2.05

Statistical analysis title	25. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.73
upper limit	3.33

Statistical analysis title	26. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.18
upper limit	1.84

Statistical analysis title	27. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.61
upper limit	2.44

Statistical analysis title	28. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.27
upper limit	1.73

Statistical analysis title	29. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.74
upper limit	3.68

Statistical analysis title	30. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.76
upper limit	2.65

Statistical analysis title	31. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.79
upper limit	2.63

Statistical analysis title	32. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.69
upper limit	2.7

Statistical analysis title	33. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.53
upper limit	4.29

Statistical analysis title	34. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	2.33

Statistical analysis title	35. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.03
upper limit	2.79

Statistical analysis title	36. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.97
upper limit	2.84

Statistical analysis title	37. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.75
upper limit	4.3

Statistical analysis title	38. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.34
upper limit	2.73

Statistical analysis title	39. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.14
upper limit	1.89

Statistical analysis title	40. Tender-Joint Counts at Weeks 2, 4, 6, 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.84
upper limit	2.19

Secondary: Change from Baseline in Tender-Joint Counts at Week 12 (Descriptive Statistics)

End point title	Change from Baseline in Tender-Joint Counts at Week 12 (Descriptive Statistics)

End point description:

Twenty-eight tender/painful joint count included the following joints: shoulders, elbows, wrists, metacarpophalangeal joints, proximal interphalangeal joints, and knees. Artificial joints were not assessed. These joints were assessed by a joint assessor, who was blinded to the participant's safety data, previous efficacy data and treatment randomization, to determine the number of joints that were considered tender or painful, and swollen.

FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF-04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Week 12 (taper period)

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	41	44	43
Units: Joints				
arithmetic mean (standard deviation)	-6.25 (± 6.77)	-7.24 (± 6.13)	-6.16 (± 6.4)	-6.47 (± 7.54)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	43	41	
Units: Joints				
arithmetic mean (standard deviation)	-7.07 (± 5.89)	-8.16 (± 4.66)	-5.59 (± 6.67)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Swollen-Joint Counts at Weeks 2, 4, 6, and 8 (comparisons to placebo, and prednisone 10 mg)

End point title	Change from Baseline in Swollen-Joint Counts at Weeks 2, 4, 6, and 8 (comparisons to placebo, and prednisone 10 mg)

End point description:

Twenty-eight tender/painful joint count included the following joints: shoulders, elbows, wrists, metacarpophalangeal joints, proximal interphalangeal joints, and knees. Artificial joints were not assessed. These joints were assessed by a joint assessor, who was blinded to the participant's safety data, previous efficacy data and treatment randomization, to determine the number of joints that were considered tender or painful, and swollen.

FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Weeks 2, 4, 6, and 8

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	45	48
Units: Joints				
least squares mean (standard error)				
Week 2	-3.42 (± 0.62)	-4.7 (± 0.61)	-4.27 (± 0.62)	-5.36 (± 0.61)
Week 4	-5.54 (± 0.7)	-5.85 (± 0.71)	-5.94 (± 0.7)	-7 (± 0.7)
Week 6	-6.26 (± 0.69)	-6.9 (± 0.7)	-7.36 (± 0.69)	-7.68 (± 0.69)
Week 8	-6.5 (± 0.79)	-7.45 (± 0.8)	-7.95 (± 0.79)	-7.83 (± 0.79)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	46	47	
Units: Joints				
least squares mean (standard error)				
Week 2	-3.65 (± 0.62)	-5.04 (± 0.61)	-2.25 (± 0.62)	
Week 4	-5.75 (± 0.71)	-6.71 (± 0.7)	-3.87 (± 0.7)	
Week 6	-6.89 (± 0.69)	-8.02 (± 0.69)	-4.94 (± 0.69)	
Week 8	-6.9 (± 0.79)	-8.38 (± 0.78)	-4.51 (± 0.8)	

Statistical analyses

Statistical analysis title	1. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured

covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.91
upper limit	0.56

Statistical analysis title	2. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.17
upper limit	-0.73

Statistical analysis title	3. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.03

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.76
upper limit	-0.29

Statistical analysis title	4. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.82
upper limit	-1.4

Statistical analysis title	5. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.13
upper limit	0.33

Statistical analysis title	6. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.52
upper limit	-1.07

Statistical analysis title	7. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.63
upper limit	0.29

Statistical analysis title	8. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.94
upper limit	-0.01

Statistical analysis title	9. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.03
upper limit	-0.11

Statistical analysis title	10. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.09
upper limit	-1.17

Statistical analysis title	11. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.85
upper limit	0.09

Statistical analysis title	12. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.79
upper limit	-0.88

Statistical analysis title	13. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.25
upper limit	0.6

Statistical analysis title	14. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.9
upper limit	-0.04

Statistical analysis title	15. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.35
upper limit	-0.5

Statistical analysis title	16. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.66
upper limit	-0.83

Statistical analysis title	17. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.88
upper limit	-0.03

Statistical analysis title	18. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5
upper limit	-1.17

Statistical analysis title	19. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	0.21

Statistical analysis title	20. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.17
upper limit	-0.72

Statistical analysis title	21. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.65
upper limit	-1.23

Statistical analysis title	22. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.52
upper limit	-1.12

Statistical analysis title	23. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 5 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.6
upper limit	-0.18

Statistical analysis title	24. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.07
upper limit	-1.68

Statistical analysis title	25. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	3.34

Statistical analysis title	26. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.36
upper limit	2.05

Statistical analysis title	27. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.94
upper limit	2.48

Statistical analysis title	28. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.01
upper limit	1.38

Statistical analysis title	29. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.79
upper limit	3.12

Statistical analysis title	30. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	2.82

Statistical analysis title	31. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.19
upper limit	2.72

Statistical analysis title	32. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.24
upper limit	1.66

Statistical analysis title	33. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.16
upper limit	3.67

Statistical analysis title	34. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.81
upper limit	3.04

Statistical analysis title	35. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.26
upper limit	2.57

Statistical analysis title	36. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.57
upper limit	2.25

Statistical analysis title	37. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.31
upper limit	4.07

Statistical analysis title	38. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.28
upper limit	3.13

Statistical analysis title	39. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.76
upper limit	2.62

Statistical analysis title	40. Swollen-Joint Counts at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.63
upper limit	2.74

Secondary: Change from Baseline in Swollen-Joint Counts at Week 12 (Descriptive Statistics)

End point title	Change from Baseline in Swollen-Joint Counts at Week 12 (Descriptive Statistics)

End point description:

Twenty-eight tender/painful joint count included the following joints: shoulders, elbows, wrists, metacarpophalangeal joints, proximal interphalangeal joints, and knees. Artificial joints were not assessed. These joints were assessed by a joint assessor, who was blinded to the participant's safety data, previous efficacy data and treatment randomization, to determine the number of joints that were considered tender or painful, and swollen.

FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF-04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Week 12 (taper period)

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	41	44	43
Units: Joints				
arithmetic mean (standard deviation)	-6.2 (± 6.21)	-5.98 (± 4.81)	-5.86 (± 6.17)	-5.58 (± 6.24)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	43	41	
Units: Joints				
arithmetic mean (standard deviation)	-7.43 (± 5.82)	-7.07 (± 5.02)	-6.17 (± 5.48)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in C-Reactive Protein (CRP) at Weeks 2, 4, 6, and 8 (comparisons to placebo and prednisone 10 mg)

End point title	Change from Baseline in C-Reactive Protein (CRP) at Weeks 2, 4, 6, and 8 (comparisons to placebo and prednisone 10 mg)

End point description:

The CRP was collected at each applicable clinic visit and analyzed by a central laboratory.
FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:
Weeks 2, 4, 6, and 8

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	45	48
Units: mg/L				
least squares mean (standard error)				
Week 2	-7.29 (± 2.89)	-12.95 (± 2.82)	-13.73 (± 2.87)	-18.92 (± 2.78)
Week 4	-9.77 (± 2.77)	-14.33 (± 2.78)	-11.52 (± 2.81)	16.57 (± 2.75)
Week 6	-9.35 (± 2.51)	-16.16 (± 2.53)	-13.05 (± 2.49)	-13.81 (± 2.51)
Week 8	-7.29 (± 2.49)	-14.28 (± 2.52)	-14.86 (± 2.47)	-11.98 (± 2.49)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	46	47	
Units: mg/L				
least squares mean (standard error)				
Week 2	-8.25 (± 2.87)	-16.9 (± 2.86)	-2.8 (± 2.89)	
Week 4	-3.92 (± 2.81)	-17.49 (± 2.76)	-6.35 (± 2.77)	
Week 6	-6.54 (± 2.52)	-16.85 (± 2.46)	-3.93 (± 2.53)	
Week 8	-7.23 (± 2.5)	-17.59 (± 2.44)	-4.19 (± 2.49)	

Statistical analyses

Statistical analysis title	1. CRP at Weeks 2, 4, 6 and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-4.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.52
upper limit	3.55

Statistical analysis title	2. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-10.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.1
upper limit	-2.2

Statistical analysis title	3. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-10.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.94
upper limit	-2.92

Statistical analysis title	4. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-16.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.01
upper limit	-8.24

Statistical analysis title	5. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-5.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.45
upper limit	2.56

Statistical analysis title	6. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-14.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.09
upper limit	-6.11

Statistical analysis title	7. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.13
upper limit	4.29

Statistical analysis title	8. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-7.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.7
upper limit	-0.26

Statistical analysis title	9. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-5.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.93
upper limit	2.59

Statistical analysis title	10. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-10.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.9
upper limit	-2.54

Statistical analysis title	11. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	2.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.32
upper limit	10.19

Statistical analysis title	12. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-11.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.83
upper limit	-3.45

Statistical analysis title	13. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-5.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.44
upper limit	1.59

Statistical analysis title	14. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-12.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.27
upper limit	-5.2

Statistical analysis title	15. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-9.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.11
upper limit	-2.14

Statistical analysis title	16. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo

Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-9.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.89
upper limit	-2.88

Statistical analysis title	17. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.63
upper limit	4.4

Statistical analysis title	18. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-12.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.88
upper limit	-5.98

Statistical analysis title	19. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.03
upper limit	3.83

Statistical analysis title	20. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-10.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.06
upper limit	-3.13

Statistical analysis title	21. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-10.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.57
upper limit	-3.77

Statistical analysis title	22. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-7.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.72
upper limit	-0.86

Statistical analysis title	23. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.98
upper limit	3.89

Statistical analysis title	24. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-13.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.27
upper limit	-6.54

Statistical analysis title	25. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	9.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.62
upper limit	17.61

Statistical analysis title	26. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	3.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.96
upper limit	11.85

Statistical analysis title	27. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	3.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	11.13

Statistical analysis title	28. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.86
upper limit	5.81

Statistical analysis title	29. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	7.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.03
upper limit	15.42

Statistical analysis title	30. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	3.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.54
upper limit	10.87

Statistical analysis title	31. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	5.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.77
upper limit	13.71

Statistical analysis title	32. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.75
upper limit	8.59

Statistical analysis title	33. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	7.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	14.43

Statistical analysis title	34. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.26
upper limit	7.64

Statistical analysis title	35. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.09
upper limit	10.7

Statistical analysis title	36. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	10.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.43
upper limit	17.18

Statistical analysis title	37. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	10.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.43
upper limit	17.18

Statistical analysis title	38. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	3.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.59
upper limit	10.22

Statistical analysis title	39. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	2.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.1
upper limit	9.57

Statistical analysis title	40. CRP at Weeks 2, 4, 6, and 8

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	5.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.25
upper limit	12.48

Secondary: Change from Baseline of CRP at Week 12 (Descriptive Statistics)

End point title	Change from Baseline of CRP at Week 12 (Descriptive Statistics)

End point description:

The CRP was collected at each applicable clinic visit and analyzed by a central laboratory.

FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Week 12 (taper period)

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	39	43	42
Units: mg/L				
arithmetic mean (standard deviation)	0.72 (± 27.4)	-6.24 (± 23.06)	-4.52 (± 20.35)	-0.64 (± 29.08)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	43	42	39	
Units: mg/L				
arithmetic mean (standard deviation)	-2.9 (± 16.1)	-9.39 (± 36.1)	-4.07 (± 22.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Patient Global Assessment of Arthritis at Weeks 2, 4, 6, and 8 (comparisons to placebo, and prednisone 10 mg)

End point title	Change from Baseline in Patient Global Assessment of Arthritis at Weeks 2, 4, 6, and 8 (comparisons to placebo, and prednisone 10 mg)

End point description:

Participants answered the following question, "Considering all the ways your arthritis affects you, how are you feeling today?" The subject's response was recorded using a 100 mm Visual Analog Scale (VAS), where 0 mm = no pain and 100 mm = most severe pain.

FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF-04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Weeks 2, 4, 6, and 8

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	45	48
Units: mm				
least squares mean (standard error)				
Week 2	-10.24 (± 2.85)	-18.77 (± 2.79)	-24.72 (± 2.83)	-22.5 (± 2.77)
Week 4	-14.93 (± 3.21)	-24.04 (± 3.22)	-27.98 (± 3.24)	-23.14 (± 3.19)
Week 6	-18.77 (± 3.28)	-30.84 (± 3.28)	-35 (± 3.27)	-27.93 (± 3.24)
Week 8	-16.51 (± 3.49)	-29.08 (± 3.52)	-36.88 (± 3.5)	-31.32 (± 3.47)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	46	47	
Units: mm				
least squares mean (standard error)				
Week 2	-10.04 (± 2.83)	-23.51 (± 2.84)	-10.61 (± 2.85)	
Week 4	-17.16 (± 3.24)	-28.31 (± 3.24)	-14.56 (± 3.21)	
Week 6	-23.07 (± 3.27)	-32.34 (± 3.27)	-18.55 (± 3.26)	
Week 8	-25.82 (± 3.5)	-34.6 (± 3.51)	-18.36 (± 3.51)	

Statistical analyses

Statistical analysis title	1. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.56
upper limit	8.31

Statistical analysis title	2. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-8.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.01
upper limit	-0.3

Statistical analysis title	3. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-14.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.01
upper limit	-6.2

Statistical analysis title	4. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo

Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-11.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.7
upper limit	-4.06

Statistical analysis title	5. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.33
upper limit	8.48

Statistical analysis title	6. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-12.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.8
upper limit	-4.98

Statistical analysis title	7. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.31
upper limit	8.58

Statistical analysis title	8. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-9.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.43
upper limit	-0.53

Statistical analysis title	9. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-13.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.39
upper limit	-4.44

Statistical analysis title	10. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-8.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.48
upper limit	0.33

Statistical analysis title	11. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.57
upper limit	6.38

Statistical analysis title	12. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-13.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.73
upper limit	-4.78

Statistical analysis title	13. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.32
upper limit	8.88

Statistical analysis title	14. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-12.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.39
upper limit	-3.17

Statistical analysis title	15. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-16.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.53
upper limit	-7.36

Statistical analysis title	16. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-9.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.42
upper limit	-0.34

Statistical analysis title	17.Patient Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-4.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.61
upper limit	4.57

Statistical analysis title	18. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-13.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.87
upper limit	-4.69

Statistical analysis title	19. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	11.6

Statistical analysis title	20. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-10.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.51
upper limit	-0.93

Statistical analysis title	21. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-18.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.28
upper limit	-8.77

Statistical analysis title	22. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-12.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.67
upper limit	-3.25

Statistical analysis title	23. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-7.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.21
upper limit	2.3

Statistical analysis title	24. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 10 mg v Placebo

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-16.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26
upper limit	-6.48

Statistical analysis title	25. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	13.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.34
upper limit	21.2

Statistical analysis title	26. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	4.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.12
upper limit	12.59

Statistical analysis title	27. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.1
upper limit	6.68

Statistical analysis title	28. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.79
upper limit	8.81

Statistical analysis title	29. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	13.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.39
upper limit	22.38

Statistical analysis title	30. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	4.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.73
upper limit	13.27

Statistical analysis title	31. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.68
upper limit	9.35

Statistical analysis title	32. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	5.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.77
upper limit	14.12

Statistical analysis title	33. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	13.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.44
upper limit	22.68

Statistical analysis title	34. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.64
upper limit	10.64

Statistical analysis title	35. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.76
upper limit	6.44

Statistical analysis title	36. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	4.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.65
upper limit	13.46

Statistical analysis title	37. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	18.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.34
upper limit	27.84

Statistical analysis title	38. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	5.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.27
upper limit	15.32

Statistical analysis title	39. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.03
upper limit	7.46

Statistical analysis title	40. Patient Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	3.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.42
upper limit	12.98

Secondary: Change from Baseline in Patient Global Assessment of Arthritis at Week 12 (Descriptive Statistics)

End point title	Change from Baseline in Patient Global Assessment of Arthritis at Week 12 (Descriptive Statistics)

End point description:

Participants answered the following question, "Considering all the ways your arthritis affects you, how are you feeling today?" The subject's response was recorded using a 100 mm Visual Analog Scale (VAS), where 0 mm = no pain and 100 mm = most severe pain.

FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF-04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Week 12 (taper period)

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	41	44	43
Units: mm				
arithmetic mean (standard deviation)	-14.54 (± 27.33)	-22.26 (± 26.11)	-18.1 (± 25.35)	-16.74 (± 31.57)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	42	41	
Units: mm				
arithmetic mean (standard deviation)	-19.24 (± 29.32)	-25.29 (± 29.2)	-17.9 (± 23.14)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Physician Global Assessment of Arthritis at Weeks 2, 4, 6, and 8 (comparisons to placebo, and prednisone 10 mg)

End point title	Change from Baseline in Physician Global Assessment of Arthritis at Weeks 2, 4, 6, and 8 (comparisons to placebo, and prednisone 10 mg)

End point description:

The investigator assessed how the participant's overall arthritis appears at the time of the visit. This was an evaluation based on the participant's disease signs, functional capacity and physical examination, and was independent of the Patient’s Global Assessment of Arthritis. The investigator’s response was recorded using a 100 mm VAS, where 0 mm = no pain and 100 mm = most severe pain.

FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF-04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Weeks 2, 4, 6, and 8

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	45	48
Units: mm				
least squares mean (standard error)				
Week 2	-16.35 (± 2.53)	-21.74 (± 2.45)	-22.14 (± 2.48)	-25.21 (± 2.43)
Week 4	-22.25 (± 2.68)	-27.03 (± 2.64)	-30.72 (± 2.66)	-28.95 (± 2.62)
Week 6	-25.58 (± 2.68)	-32.54 (± 2.67)	-34.79 (± 2.66)	-32.79 (± 2.63)

Week 8	-26.24 (± 2.81)	-33.92 (± 2.82)	-38 (± 2.79)	-33.71 (± 2.77)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	46	47	
Units: mm				
least squares mean (standard error)				
Week 2	-13.24 (± 2.48)	-22.8 (± 2.48)	-9.29 (± 2.5)	
Week 4	-20.94 (± 2.66)	-31.16 (± 2.66)	-15 (± 2.64)	
Week 6	-28.54 (± 2.66)	-33.92 (± 2.66)	-19.48 (± 2.65)	
Week 8	-29.25 (± 2.79)	-35.5 (± 2.79)	-21.52 (± 2.79)	

Statistical analyses

Statistical analysis title	1. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-7.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.07
upper limit	-0.06

Statistical analysis title	2. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-12.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.34
upper limit	-5.56

Statistical analysis title	3. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-12.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.79
upper limit	-5.91

Statistical analysis title	4. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-15.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.79
upper limit	-9.06

Statistical analysis title	5. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.89
upper limit	2.99

Statistical analysis title	6. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-13.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.44
upper limit	-6.57

Statistical analysis title	7. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-7.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.65
upper limit	0.16

Statistical analysis title	8. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-12.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.38
upper limit	-4.68

Statistical analysis title	9. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-15.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.1
upper limit	-8.35

Statistical analysis title	10. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-13.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.27
upper limit	-6.63

Statistical analysis title	11. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-5.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.31
upper limit	1.43

Statistical analysis title	12. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-16.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.54
upper limit	-8.79

Statistical analysis title	13. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-6.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.5
upper limit	1.32

Statistical analysis title	14. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-13.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.46
upper limit	-5.65

Statistical analysis title	15. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-15.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.69
upper limit	-7.93

Statistical analysis title	16. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-13.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.66
upper limit	-5.96

Statistical analysis title	17. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-9.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.44
upper limit	-1.68

Statistical analysis title	18. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-14.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.82
upper limit	-7.06

Statistical analysis title	19. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-4.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.53
upper limit	3.09

Statistical analysis title	20. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-12.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.21
upper limit	-4.59

Statistical analysis title	21. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-16.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.25
upper limit	-8.71

Statistical analysis title	22. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Placebo

Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-12.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.94
upper limit	-4.44

Statistical analysis title	23. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-7.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.5
upper limit	0.04

Statistical analysis title	24. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-13.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.75
upper limit	-6.21

Statistical analysis title	25. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	6.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.53
upper limit	13.42

Statistical analysis title	26. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.81
upper limit	7.92

Statistical analysis title	27. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.25
upper limit	7.57

Statistical analysis title	28. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.26
upper limit	4.42

Statistical analysis title	29. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	8.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.48
upper limit	16.35

Statistical analysis title	30. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	4.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.24
upper limit	11.51

Statistical analysis title	31. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.96
upper limit	7.84

Statistical analysis title	32. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	2.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.14
upper limit	9.56

Statistical analysis title	33. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	8.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	15.77

Statistical analysis title	34. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.03
upper limit	8.8

Statistical analysis title	35. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.26
upper limit	6.52

Statistical analysis title	36. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.23
upper limit	8.49

Statistical analysis title	37. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	9.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.46
upper limit	17.06

Statistical analysis title	38. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.23
upper limit	9.38

Statistical analysis title	39. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.27
upper limit	5.27

Statistical analysis title	40. Physician Global Assessment of Arthritis

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.95
upper limit	9.53

Secondary: Change from Baseline in Physician Global Assessment of Arthritis at Week 12 (Descriptive Statistics)

End point title	Change from Baseline in Physician Global Assessment of Arthritis at Week 12 (Descriptive Statistics)

End point description:

The investigator assessed how the participant's overall arthritis appears at the time of the visit. This was an evaluation based on the participant's disease signs, functional capacity and physical examination, and was independent of the Patient's Global Assessment of Arthritis. The investigator's response was recorded using a 100 mm VAS, where 0 mm = no pain and 100 mm = most severe pain.
FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Week 12 (taper period)

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	41	44	43
Units: mm				
arithmetic mean (standard deviation)	-25 (± 21.57)	-28.56 (± 26.41)	-23.04 (± 22)	-24.3 (± 28.15)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	

Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	42	40	
Units: mm				
arithmetic mean (standard deviation)	-27.25 (± 23.71)	-27.25 (± 20.42)	-19.34 (± 27.21)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in pain VAS at Weeks 2, 4, 6, and 8 (comparisons to placebo, and prednisone 10 mg)

End point title	Change from Baseline in pain VAS at Weeks 2, 4, 6, and 8 (comparisons to placebo, and prednisone 10 mg)

End point description:

Participants assessed the severity of their arthritis pain using a 100 mm VAS placing a mark on the scale between 0 (no pain) and 100 (most severe pain), which corresponds to the magnitude of their pain. FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Weeks 2, 4, 6, and 8

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	45	48
Units: mm				
least squares mean (standard error)				
Week 2	-13.41 (± 2.88)	-17.4 (± 2.83)	-24.9 (± 2.86)	-22.86 (± 2.8)
Week 4	-15.55 (± 3.08)	-24.38 (± 3.09)	-29.7 (± 3.1)	-26.08 (± 3.05)
Week 6	-19.03 (± 3.33)	-29.16 (± 3.35)	-34.37 (± 3.33)	-30.15 (± 3.3)
Week 8	-18.95 (± 3.45)	-28.53 (± 3.5)	-37.96 (± 3.46)	-30.91 (± 3.43)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	46	47	
Units: mm				
least squares mean (standard error)				
Week 2	-12.68 (± 2.86)	-24.59 (± 2.87)	-10.54 (± 2.88)	
Week 4	-20.26 (± 3.1)	-29.65 (± 3.11)	-14.28 (± 3.08)	

Week 6	-24.16 (± 3.33)	-34.69 (± 3.34)	-18.8 (± 3.32)	
Week 8	-25.86 (± 3.46)	-37.6 (± 3.47)	-18.26 (± 3.47)	

Statistical analyses

Statistical analysis title	1. Change from Baseline in pain VAS

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.89
upper limit	5.14

Statistical analysis title	2. Change from Baseline in pain VAS

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-6.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.8
upper limit	1.08

Statistical analysis title	3. Change from Baseline in pain VAS

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-14.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.34
upper limit	-6.38

Statistical analysis title	4. Change from Baseline in pain VAS

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-12.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.22
upper limit	-4.41

Statistical analysis title	5. Change from Baseline in pain VAS

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.12
upper limit	5.85

Statistical analysis title	6. Change from Baseline in pain VAS

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-14.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.05
upper limit	-6.04

Statistical analysis title	7. Change from Baseline in pain VAS

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.83
upper limit	7.3

Statistical analysis title	8. Change from Baseline in pain VAS

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-10.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.67
upper limit	-1.53

Statistical analysis title	9. Change from Baseline in pain VAS

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-15.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.01
upper limit	-6.82

Statistical analysis title	10. Change from Baseline in pain VAS

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo

Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-11.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.33
upper limit	-3.26

Statistical analysis title	11. Change from Baseline in pain VAS

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-5.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.57
upper limit	2.62

Statistical analysis title	12. Change from Baseline in pain VAS

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-15.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.98
upper limit	-6.76

Statistical analysis title	13. Change from Baseline in pain VAS

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.49
upper limit	9.03

Statistical analysis title	14. Change from Baseline in pain VAS

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-10.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.64
upper limit	-1.08

Statistical analysis title	15. Change from Baseline in pain VAS

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-15.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.83
upper limit	-6.32

Statistical analysis title	16. Change from Baseline in pain VAS

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-11.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.56
upper limit	-2.13

Statistical analysis title	17. Change from Baseline in pain VAS

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-5.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.61
upper limit	3.89

Statistical analysis title	18. Change from Baseline in pain VAS

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-15.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.15
upper limit	-6.61

Statistical analysis title	19. Change from Baseline in pain VAS

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.32
upper limit	8.94

Statistical analysis title	20. Change from Baseline in pain VAS

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Placebo

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-10.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.95
upper limit	-0.59

Statistical analysis title	21. Change from Baseline in pain VAS

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-19.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.34
upper limit	-10.06

Statistical analysis title	22. Change from Baseline in pain VAS

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-12.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.25
upper limit	-3.04

Statistical analysis title	23. Change from Baseline in pain VAS

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-7.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.24
upper limit	2.04

Statistical analysis title	24. Change from Baseline in pain VAS

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-19.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.99
upper limit	-9.68

Statistical analysis title	25. Change from Baseline in pain VAS

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	11.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.18
upper limit	19.16

Statistical analysis title	26. Change from Baseline in pain VAS

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	7.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.78
upper limit	15.15

Statistical analysis title	27. Change from Baseline in pain VAS

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.28
upper limit	7.65

Statistical analysis title	28. Change from Baseline in pain VAS

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.14
upper limit	9.61

Statistical analysis title	29. Change from Baseline in pain VAS

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	14.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.51
upper limit	22.71

Statistical analysis title	30. Change from Baseline in pain VAS

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	5.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.38
upper limit	13.92

Statistical analysis title	31. Change from Baseline in pain VAS

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.68
upper limit	8.59

Statistical analysis title	32. Change from Baseline in pain VAS

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	3.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.99
upper limit	12.15

Statistical analysis title	33. Change from Baseline in pain VAS

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	15.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.38
upper limit	24.93

Statistical analysis title	34. Change from Baseline in pain VAS

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	5.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.81
upper limit	14.86

Statistical analysis title	35. Change from Baseline in pain VAS

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.97
upper limit	9.59

Statistical analysis title	36. Change from Baseline in pain VAS

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	4.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.69
upper limit	13.77

Statistical analysis title	37. Change from Baseline in pain VAS

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	18.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.03
upper limit	28.27

Statistical analysis title	38. Change from Baseline in pain VAS

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	9.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.64
upper limit	18.78

Statistical analysis title	39. Change from Baseline in pain VAS

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	9.28

Statistical analysis title	40. Change from Baseline in pain VAS

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	6.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.91
upper limit	16.29

Secondary: Change from Baseline in Pain VAS at Week 12 (Descriptive Statistics)

End point title	Change from Baseline in Pain VAS at Week 12 (Descriptive Statistics)

End point description:

Participants assessed the severity of their arthritis pain using a 100 mm VAS placing a mark on the scale between 0 (no pain) and 100 (most severe pain), which corresponds to the magnitude of their pain. FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Week 12 (taper period)

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	40	44	43
Units: mm				
arithmetic mean (standard deviation)	-17.86 (± 26.7)	-19.4 (± 29.04)	-18.23 (± 27.75)	-16.6 (± 30.5)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	42	41	
Units: mm				
arithmetic mean (standard deviation)	-21.52 (± 24.69)	-25.17 (± 29.6)	-16.3 (± 22.41)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in HAQ-DI at Weeks 2, 4, 6, and 8 (comparisons to placebo, and prednisone 10 mg)

End point title	Change from Baseline in HAQ-DI at Weeks 2, 4, 6, and 8 (comparisons to placebo, and prednisone 10 mg)

End point description:

Health Assessment Questionnaire-Disability Index (HAQ-DI): participant-reported assessment of ability to perform tasks in 8 categories of daily living activities: dress/groom; arise; eat; walk; reach; grip; hygiene; and common activities over past week. Each item scored on 4-point scale from 0 to 3: 0=no difficulty; 1=some difficulty; 2=much difficulty; 3=unable to do. Overall score was computed as the sum of domain scores and divided by the number of domains answered. Total possible score range 0-3 where 0 = least difficulty and 3 = extreme difficulty.
FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF-04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Weeks 2, 4, 6, and 8

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	45	48
Units: Units on a scale				
least squares mean (standard error)				
Week 2	-0.25 (± 0.06)	-0.34 (± 0.06)	-0.33 (± 0.06)	-0.41 (± 0.06)
Week 4	-0.26 (± 0.07)	-0.5 (± 0.07)	-0.43 (± 0.07)	-0.51 (± 0.07)
Week 6	-0.35 (± 0.07)	-0.6 (± 0.07)	-0.52 (± 0.07)	-0.56 (± 0.07)
Week 8	-0.26 (± 0.08)	-0.59 (± 0.08)	-0.6 (± 0.08)	-0.55 (± 0.08)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	46	47	
Units: Units on a scale				
least squares mean (standard error)				
Week 2	-0.23 (± 0.06)	-0.41 (± 0.06)	-0.05 (± 0.06)	
Week 4	-0.34 (± 0.07)	-0.58 (± 0.07)	-0.14 (± 0.07)	
Week 6	-0.39 (± 0.07)	-0.68 (± 0.07)	-0.21 (± 0.07)	
Week 8	-0.5 (± 0.08)	-0.77 (± 0.08)	-0.19 (± 0.08)	

Statistical analyses

Statistical analysis title	1. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.37
upper limit	-0.02

Statistical analysis title	2. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.46
upper limit	-0.11

Statistical analysis title	3. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.45
upper limit	-0.1

Statistical analysis title	4. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.52
upper limit	-0.18

Statistical analysis title	5. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.35
upper limit	0

Statistical analysis title	6. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.53
upper limit	-0.18

Statistical analysis title	7. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.31
upper limit	0.07

Statistical analysis title	8. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.54
upper limit	-0.17

Statistical analysis title	9. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.47
upper limit	-0.09

Statistical analysis title	10. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.56
upper limit	-0.18

Statistical analysis title	11. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.39
upper limit	-0.01

Statistical analysis title	12. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.63
upper limit	-0.25

Statistical analysis title	13. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.34
upper limit	0.05

Statistical analysis title	14. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.59
upper limit	-0.2

Statistical analysis title	15. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.51
upper limit	-0.12

Statistical analysis title	16. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo

Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.55
upper limit	-0.16

Statistical analysis title	17. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.38
upper limit	0.01

Statistical analysis title	18. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.67
upper limit	-0.27

Statistical analysis title	19. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	0.15

Statistical analysis title	20. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.63
upper limit	-0.18

Statistical analysis title	21. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.64
upper limit	-0.18

Statistical analysis title	22. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.59
upper limit	-0.14

Statistical analysis title	23. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.54
upper limit	-0.09

Statistical analysis title	24. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.81
upper limit	-0.35

Statistical analysis title	25. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.01
upper limit	0.34

Statistical analysis title	26. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.24

Statistical analysis title	27. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.25

Statistical analysis title	28. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.17
upper limit	0.18

Statistical analysis title	29. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.13
upper limit	0.51

Statistical analysis title	30. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.11
upper limit	0.27

Statistical analysis title	31. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.04
upper limit	0.34

Statistical analysis title	32. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.13
upper limit	0.25

Statistical analysis title	33. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.13
upper limit	0.52

Statistical analysis title	34. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.12
upper limit	0.27

Statistical analysis title	35. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.05
upper limit	0.35

Statistical analysis title	36. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.08
upper limit	0.31

Statistical analysis title	37. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.28
upper limit	0.73

Statistical analysis title	38. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.05
upper limit	0.4

Statistical analysis title	39. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.06
upper limit	0.4

Statistical analysis title	40. Change from Baseline in HAQ-DI

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.01
upper limit	0.44

Secondary: Change from Baseline in HAQ-DI at Week 12 (Descriptive Statistics)

End point title	Change from Baseline in HAQ-DI at Week 12 (Descriptive Statistics)

End point description:

Health Assessment Questionnaire-Disability Index (HAQ-DI): participant-reported assessment of ability to perform tasks in 8 categories of daily living activities: dress/groom; arise; eat; walk; reach; grip; hygiene; and common activities over past week. Each item scored on 4-point scale from 0 to 3: 0=no difficulty; 1=some difficulty; 2=much difficulty; 3=unable to do. Overall score was computed as the sum

of domain scores and divided by the number of domains answered. Total possible score range 0-3 where 0 = least difficulty and 3 = extreme difficulty.
FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF-04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Week 12 (taper period)

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	41	44	43
Units: Units on a scale				
arithmetic mean (standard deviation)	-0.28 (± 0.63)	-0.57 (± 0.65)	-0.37 (± 0.5)	-0.38 (± 0.5)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	42	41	
Units: Units on a scale				
arithmetic mean (standard deviation)	-0.52 (± 0.63)	-0.56 (± 0.59)	-0.26 (± 0.56)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in disease activity score (DAS) 28-3 CRP at Weeks 2, 4, 6, and 8 (comparisons to placebo, and prednisone 10 mg)

End point title	Change from Baseline in disease activity score (DAS) 28-3 CRP at Weeks 2, 4, 6, and 8 (comparisons to placebo, and prednisone 10 mg)

End point description:

DAS28-3 (CRP) was calculated from the SJC and TJC using the 28 joints count and CRP (mg/L). Total score range: 0 to 9.4, higher score indicated higher disease activity. DAS28-3 (CRP) <= 3.2 implied low disease activity and >3.2 to 5.1 implied moderate to high disease activity, and DAS28-3 (CRP) <2.6 = remission. FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF-04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Weeks 2, 4, 6, and 8

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	45	48
Units: Units on a scale				
least squares mean (standard error)				
Week 2	-0.81 (± 0.13)	-1.15 (± 0.13)	-1.21 (± 0.13)	-1.51 (± 0.13)
Week 4	-1.19 (± 0.15)	-1.49 (± 0.15)	-1.71 (± 0.15)	-1.73 (± 0.15)
Week 6	-1.38 (± 0.16)	-1.81 (± 0.16)	-2.01 (± 0.16)	-1.99 (± 0.16)
Week 8	-1.44 (± 0.17)	-1.84 (± 0.17)	-2.22 (± 0.17)	-2.13 (± 0.17)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	46	47	
Units: Units on a scale				
least squares mean (standard error)				
Week 2	-0.75 (± 0.13)	-1.23 (± 0.13)	-0.4 (± 0.13)	
Week 4	-1.01 (± 0.15)	-1.67 (± 0.15)	-0.76 (± 0.15)	
Week 6	-1.37 (± 0.16)	-1.98 (± 0.16)	-0.94 (± 0.16)	
Week 8	-1.42 (± 0.17)	-2.14 (± 0.17)	-0.93 (± 0.17)	

Statistical analyses

Statistical analysis title	1. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.78
upper limit	-0.04

Statistical analysis title	2. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model

with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.12
upper limit	-0.39

Statistical analysis title	3. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.18
upper limit	-0.44

Statistical analysis title	4. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo

Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.48
upper limit	-0.74

Statistical analysis title	5. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Placebo v Prednisone 5 mg
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.72
upper limit	0.02

Statistical analysis title	6. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.19
upper limit	-0.46

Statistical analysis title	7. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.85
upper limit	0

Statistical analysis title	8. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.15
upper limit	-0.31

Statistical analysis title	9. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.37
upper limit	-0.52

Statistical analysis title	10. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.39
upper limit	-0.54

Statistical analysis title	11. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.67
upper limit	0.18

Statistical analysis title	12. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.33
upper limit	-0.49

Statistical analysis title	13. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	0.02

Statistical analysis title	14. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.32
upper limit	-0.41

Statistical analysis title	15. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.53
upper limit	-0.62

Statistical analysis title	16. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.51
upper limit	-0.6

Statistical analysis title	17. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.89
upper limit	0.03

Statistical analysis title	18. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	-0.59

Statistical analysis title	19. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	-0.03

Statistical analysis title	20. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	-0.43

Statistical analysis title	21. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.77
upper limit	-0.8

Statistical analysis title	22. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.69
upper limit	-0.72

Statistical analysis title	23. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.98
upper limit	-0.01

Statistical analysis title	24. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 10 mg v Placebo

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.69
upper limit	-0.73

Statistical analysis title	25. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.04
upper limit	0.78

Statistical analysis title	26. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.29
upper limit	0.44

Statistical analysis title	27. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.35
upper limit	0.38

Statistical analysis title	28. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.65
upper limit	0.08

Statistical analysis title	29. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	0.91

Statistical analysis title	30. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.24
upper limit	0.6

Statistical analysis title	31. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.46
upper limit	0.38

Statistical analysis title	32. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.48
upper limit	0.37

Statistical analysis title	33. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.15
upper limit	1.06

Statistical analysis title	34. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.28
upper limit	0.63

Statistical analysis title	35. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.49
upper limit	0.42

Statistical analysis title	36. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.47
upper limit	0.44

Statistical analysis title	37. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.22
upper limit	1.18

Statistical analysis title	38. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.18
upper limit	0.78

Statistical analysis title	39. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.55
upper limit	0.4

Statistical analysis title	40. Change from Baseline in DAS 28-3 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.47
upper limit	0.49

Secondary: Change from Baseline in DAS 28-3 CRP at Week 12 (Descriptive Statistics)

End point title	Change from Baseline in DAS 28-3 CRP at Week 12 (Descriptive Statistics)

End point description:

DAS28-3 (CRP) was calculated from the SJC and TJC using the 28 joints count and CRP (mg/L). Total score range: 0 to 9.4, higher score indicated higher disease activity. DAS28-3 (CRP) <= 3.2 implied low disease activity and >3.2 to 5.1 implied moderate to high disease activity, and DAS28-3 (CRP) <2.6 = remission.
FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Week 12 (taper period)

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	41	44	41
Units: Units on a scale				
arithmetic mean (standard deviation)	-1.3 (± 1.21)	-1.37 (± 1.05)	-1.29 (± 1.14)	-1.25 (± 1.36)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	43	40	
Units: Units on a scale				
arithmetic mean (standard deviation)	-1.45 (± 1.05)	-1.62 (± 1)	-1.13 (± 1.08)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in DAS28-4(CRP) at Weeks 2, 4, 6, and 8 (comparisons to placebo, and prednisone 10 mg)

End point title	Change from Baseline in DAS28-4(CRP) at Weeks 2, 4, 6, and 8 (comparisons to placebo, and prednisone 10 mg)

End point description:

DAS28-4 (CRP) was calculated from the SJC and TJC using the 28 joints count and CRP (mg/L). Total score range: 0 to 9.4, higher score indicated higher disease activity. DAS28-3 (CRP) <= 3.2 implied low disease activity and >3.2 to 5.1 implied moderate to high disease activity, and DAS28-3 (CRP) <2.6 = remission. All statistics presented below are derived from mixed model with fixed effects for treatment, visit, treatment-by-visit interaction and baseline value; unstructured covariance matrix was used.
FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Weeks 2, 4, 6, and 8

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	45	48
Units: Units on a scale				
least squares mean (standard error)				
Week 2	-0.88 (± 0.14)	-1.29 (± 0.14)	-1.45 (± 0.14)	-1.69 (± 0.14)
Week 4	-1.29 (± 0.16)	-1.68 (± 0.16)	-1.97 (± 0.16)	-1.9 (± 0.16)
Week 6	-1.51 (± 0.18)	-2.06 (± 0.18)	-2.32 (± 0.18)	-2.21 (± 0.18)
Week 8	-1.55 (± 0.19)	-2.07 (± 0.19)	-2.53 (± 0.19)	-2.38 (± 0.19)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	46	47	
Units: Units on a scale				
least squares mean (standard error)				
Week 2	-0.82 (± 0.14)	-1.46 (± 0.14)	-0.52 (± 0.14)	
Week 4	-1.15 (± 0.16)	-1.92 (± 0.16)	-0.9 (± 0.16)	
Week 6	-1.56 (± 0.18)	-2.27 (± 0.18)	-1.12 (± 0.18)	
Week 8	-1.65 (± 0.19)	-2.44 (± 0.19)	-1.11 (± 0.19)	

Statistical analyses

Statistical analysis title	1. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.76
upper limit	0.03

Statistical analysis title	2. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.17
upper limit	-0.39

Statistical analysis title	3. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.32
upper limit	-0.54

Statistical analysis title	4. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.56
upper limit	-0.78

Statistical analysis title	5. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	0.09

Statistical analysis title	6. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.34
upper limit	-0.55

Statistical analysis title	7. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.84
upper limit	0.07

Statistical analysis title	8. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.23
upper limit	-0.32

Statistical analysis title	9. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.52
upper limit	-0.61

Statistical analysis title	10. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.45
upper limit	-0.54

Statistical analysis title	11. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.71
upper limit	0.21

Statistical analysis title	12. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.48
upper limit	-0.57

Statistical analysis title	13. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.89
upper limit	0.11

Statistical analysis title	14. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.44
upper limit	-0.45

Statistical analysis title	15. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.71
upper limit	-0.71

Statistical analysis title	16. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.59
upper limit	-0.59

Statistical analysis title	17. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.95
upper limit	0.05

Statistical analysis title	18. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.65
upper limit	-0.66

Statistical analysis title	19. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.96
upper limit	0.08

Statistical analysis title	20. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.48
upper limit	-0.44

Statistical analysis title	21. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.94
upper limit	-0.91

Statistical analysis title	22. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Placebo

Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	-0.76

Statistical analysis title	23. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.06
upper limit	-0.03

Statistical analysis title	24. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.85
upper limit	-0.81

Statistical analysis title	25. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.19
upper limit	0.98

Statistical analysis title	26. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.22
upper limit	0.56

Statistical analysis title	27. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.38
upper limit	0.41

Statistical analysis title	28. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 2 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.62
upper limit	0.16

Statistical analysis title	29. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.18
upper limit	1.09

Statistical analysis title	30. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.21
upper limit	0.7

Statistical analysis title	31. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	0.42

Statistical analysis title	32. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.43
upper limit	0.48

Statistical analysis title	33. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.26
upper limit	1.26

Statistical analysis title	34. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.29
upper limit	0.7

Statistical analysis title	35. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.55
upper limit	0.44

Statistical analysis title	36. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 6 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.43
upper limit	0.56

Statistical analysis title	37. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	1.41

Statistical analysis title	38. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.15
upper limit	0.89

Statistical analysis title	39. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 10 mg v PF-04171327 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.61
upper limit	0.42

Statistical analysis title	40. Change from Baseline in DAS28-4 CRP

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.46
upper limit	0.57

Secondary: Change from Baseline in DAS28-4(CRP) at Week 12 (Descriptive Statistics)

End point title	Change from Baseline in DAS28-4(CRP) at Week 12 (Descriptive Statistics)

End point description:

DAS28-4 (CRP) was calculated from the SJC and TJC using the 28 joints count and CRP (mg/L). Total score range: 0 to 9.4, higher score indicated higher disease activity. DAS28-3 (CRP) <= 3.2 implied low disease activity and >3.2 to 5.1 implied moderate to high disease activity, and DAS28-3 (CRP) <2.6 = remission.
FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Week 12 (taper period)

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	41	44	41
Units: Units on a scale				
arithmetic mean (standard deviation)	-1.39 (± 1.31)	-1.56 (± 1.17)	-1.42 (± 1.19)	-1.38 (± 1.47)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	

Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	42	40	
Units: Units on a scale				
arithmetic mean (standard deviation)	-1.59 (± 1.22)	-1.8 (± 1.14)	-1.29 (± 1.21)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36v2 mental component scores at Weeks 4 and 8 (comparisons to placebo, and prednisone 10 mg)

End point title	Change from Baseline in SF-36v2 mental component scores at Weeks 4 and 8 (comparisons to placebo, and prednisone 10 mg)

End point description:

The 36 item Short Form Health Survey (SF-36) (Versions 2, acute version) is a 36 item generic health status measure. It measures 8 general health concepts: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. These concepts can also be summarized as physical component score (PCS) and mental component score (MCS). The score for a section is an average of the individual question scores, which are scaled 0-100 (100=highest level of functioning). This questionnaire was completed by participant prior to any procedures being performed at the visit, if possible. The form was then checked by site staff for completeness.
FAS was used for this analysis. FAS included all participants who were randomized to the study and received at least one dose of the randomized study drug (PF 04171327, prednisone, or placebo).

End point type	Secondary

End point timeframe:

Weeks 4 and 8

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	45	48
Units: Units on a scale				
least squares mean (standard error)				
Week 4	3.59 (± 1.28)	4.53 (± 1.26)	5.22 (± 1.3)	5.74 (± 1.25)
Week 8	2.57 (± 1.39)	6.07 (± 1.41)	6.03 (± 1.4)	6.47 (± 1.39)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	46	47	
Units: Units on a scale				
least squares mean (standard error)				
Week 4	3.67 (± 1.29)	7.23 (± 1.29)	4.98 (± 1.28)	
Week 8	5.3 (± 1.4)	8.76 (± 1.4)	4.58 (± 1.39)	

Statistical analyses

Statistical analysis title	1. SF-36v2 mental component score

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.94
upper limit	2.17

Statistical analysis title	2. SF-36v2 mental component score

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.98
upper limit	3.08

Statistical analysis title	3. SF-36v2 mental component score

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Placebo v PF-04171327 10 mg
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.34
upper limit	3.82

Statistical analysis title	4. SF-36v2 mental component score

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.75
upper limit	4.28

Statistical analysis title	5. SF-36v2 mental component score

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.88
upper limit	2.27

Statistical analysis title	6. SF-36v2 mental component score

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	2.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.32
upper limit	5.82

Statistical analysis title	7. SF-36v2 mental component score

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.89
upper limit	1.87

Statistical analysis title	8. SF-36v2 mental component score

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.41
upper limit	5.4

Statistical analysis title	9. SF-36v2 mental component score

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.44
upper limit	5.34

Statistical analysis title	10. SF-36v2 mental component score

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Placebo

Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.98
upper limit	5.76

Statistical analysis title	11. SF-36v2 mental component score

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.16
upper limit	4.61

Statistical analysis title	12. SF-36v2 mental component score

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	4.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.29
upper limit	8.06

Statistical analysis title	13. SF-36v2 mental component score

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.21
upper limit	-0.06

Statistical analysis title	14. SF-36v2 mental component score

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.25
upper limit	0.85

Statistical analysis title	15. SF-36v2 mental component score

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.63
upper limit	1.6

Statistical analysis title	16. SF-36v2 mental component score

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.02
upper limit	2.05

Statistical analysis title	17. SF-36v2 mental component score

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-6.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.07
upper limit	-2.31

Statistical analysis title	18. SF-36v2 mental component score

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.6
upper limit	1.23

Statistical analysis title	19. SF-36v2 mental component score

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.64
upper limit	1.18

Statistical analysis title	20. SF-36v2 mental component score

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.16
upper limit	1.58

Secondary: Change from Baseline in SF-36v2 mental component scores at Week 12 (Descriptive Statistics)

End point title	Change from Baseline in SF-36v2 mental component scores at Week 12 (Descriptive Statistics)

End point description:

The 36 item Short Form Health Survey (SF-36) (Versions 2, acute version) is a 36 item generic health status measure. It measures 8 general health concepts: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. These concepts can also be summarized as physical component score (PCS) and mental component score (MCS). The score for a section is an average of the individual question scores, which are scaled 0-100 (100=highest level of functioning). This questionnaire was completed by the participant prior to any procedures being performed at the visit, if possible. The form was then checked by site staff for completeness.

End point type	Secondary

End point timeframe:

Week 12 (taper period)

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	41	44	43
Units: Units on a scale				
arithmetic mean (standard deviation)	3.35 (± 11.99)	4.19 (± 9.19)	0.48 (± 8.97)	2.72 (± 10.67)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	43	42	41	
Units: Units on a scale				
arithmetic mean (standard deviation)	3.08 (± 12.91)	6.11 (± 12.9)	4.69 (± 10.72)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36v2 physical component scores at Weeks 4 and 8 (comparisons to placebo, and prednisone 10 mg)

End point title	Change from Baseline in SF-36v2 physical component scores at Weeks 4 and 8 (comparisons to placebo, and prednisone 10 mg)

End point description:

The 36 item Short Form Health Survey (SF-36) (Versions 2, acute version) is a 36 item generic health status measure. It measures 8 general health concepts: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. These concepts can also be summarized as physical component score (PCS) and mental component score (MCS). The score for a section is an average of the individual question scores, which are scaled 0-100 (100=highest level of functioning). This questionnaire was completed by the participant prior to any procedures being performed at the visit, if possible. The form was then checked by site staff for completeness.

End point type	Secondary

End point timeframe:

Weeks 4 and 8

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	45	48
Units: Units on a scale				
least squares mean (standard error)				
Week 4	3.84 (± 0.92)	5 (± 0.91)	8.22 (± 0.93)	6.83 (± 0.9)
Week 8	5.24 (± 1.03)	7.85 (± 1.04)	9.65 (± 1.03)	7.15 (± 1.02)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	46	47	
Units: Units on a scale				
least squares mean (standard error)				
Week 4	4.28 (± 0.93)	7.51 (± 0.93)	2.1 (± 0.92)	
Week 8	7.06 (± 1.03)	9.62 (± 1.03)	3.45 (± 1.03)	

Statistical analyses

Statistical analysis title	1. SF-36v2 physical component scores

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.83
upper limit	4.3

Statistical analysis title	2. SF-36v2 physical component scores

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.35
upper limit	5.45

Statistical analysis title	3. SF-36v2 physical component scores

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	6.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.54
upper limit	8.7

Statistical analysis title	4. SF-36v2 physical component scores

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	4.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.19
upper limit	7.26

Statistical analysis title	5. SF-36v2 physical component scores

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 5 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	2.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.39
upper limit	4.76

Statistical analysis title	6. SF-36v2 physical component scores

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	Prednisone 10 mg v Placebo

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	5.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.83
upper limit	7.99

Statistical analysis title	7. SF-36v2 physical component scores

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.08
upper limit	4.65

Statistical analysis title	8. SF-36v2 physical component scores

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	4.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.52
upper limit	7.28

Statistical analysis title	9. SF-36v2 physical component scores

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	6.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.33
upper limit	9.07

Statistical analysis title	10. SF-36v2 physical component scores

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	6.55

Statistical analysis title	11. SF-36v2 physical component scores

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 5 mg v Placebo

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	3.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	6.47

Statistical analysis title	12. SF-36v2 physical component scores

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	Prednisone 10 mg v Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	6.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.29
upper limit	9.04

Statistical analysis title	13. SF-36v2 physical component scores

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.27
upper limit	-1.09

Statistical analysis title	14. SF-36v2 physical component scores

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.07
upper limit	0.05

Statistical analysis title	15. SF-36v2 physical component scores

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.88
upper limit	3.3

Statistical analysis title	16. SF-36v2 physical component scores

Statistical analysis description:

Week 4 analysis presented. Statistical analysis was performed using a repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays the sum of the number of subjects randomized in each selected group . The total number of subjects used in fitting the mixed effects repeated measures model is the total number of subjects in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg

Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.23
upper limit	1.87

Statistical analysis title	17. SF-36v2 physical component scores

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 1 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-4.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.26
upper limit	-1.5

Statistical analysis title	18. SF-36v2 physical component scores

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 5 mg v Prednisone 10 mg
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.65
upper limit	1.12

Statistical analysis title	19. SF-36v2 physical component scores

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 10 mg v Prednisone 10 mg
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.84
upper limit	2.91

Statistical analysis title	20. SF-36v2 physical component scores

Statistical analysis description:

Week 8 (primary timepoint of interest) presented. Statistical analysis was performed using repeated measures mixed model with fixed effects for treatment and visit, treatment by visit interaction and baseline value; unstructured covariance matrix was used. The field 'Number of subjects included in analysis' below displays sum of number of subjects randomized in each selected group. Total number of subjects used in fitting mixed effects repeated measures model is total number of subject in FAS.

Comparison groups	PF-04171327 15 mg v Prednisone 10 mg
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.33
upper limit	0.39

Secondary: Change from Baseline in SF-36v2 physical component scores at Week 12 (Descriptive Statistics)

End point title	Change from Baseline in SF-36v2 physical component scores at Week 12 (Descriptive Statistics)

End point description:

The 36 item Short Form Health Survey (SF-36) (Versions 2, acute version) is a 36 item generic health status measure. It measures 8 general health concepts: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. These concepts can also

be summarized as physical component score (PCS) and mental component score (MCS). The score for a section is an average of the individual question scores, which are scaled 0-100 (100=highest level of functioning). This questionnaire was completed by the participant prior to any procedures being performed at the visit, if possible. The form was then checked by site staff for completeness.

End point type	Secondary

End point timeframe:

Week 12 (taper period)

End point values	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg	PF-04171327 15 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	41	44	43
Units: Units on a scale				
arithmetic mean (standard deviation)	4.64 (± 8.21)	5.39 (± 7.05)	7.42 (± 8.56)	3.91 (± 7.16)

End point values	Prednisone 5 mg	Prednisone 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	43	42	41	
Units: Units on a scale				
arithmetic mean (standard deviation)	7.63 (± 7.95)	5.85 (± 7.32)	3.23 (± 4.8)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

13 weeks

Adverse event reporting additional description:

All causality AEs and SAEs are included in this section. The same event may appear as both an AE and a SAE. However, what is presented are distinct events. An event may be categorized as serious in one participant and as nonserious in another participant, or one participant may have experienced both a serious and nonserious event during the study.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	PF-04171327 1 mg

Reporting group description:

Participants received PF-04171327 1 mg Once daily (QD) for 8 weeks. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.

Reporting group title	PF-04171327 5 mg

Reporting group description:

Participants received PF-04171327 5 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.

Reporting group title	PF-04171327 10 mg

Reporting group description:

Participants received PF-04171327 10 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.

Reporting group title	PF-04171327 15 mg

Reporting group description:

Participants received PF-04171327 15 mg QD for 8 weeks. After 8 weeks of study treatment, participants were tapered off study drug. From week 9 through 10, the participants received 1 mg PF-04171327 + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 mg PF-04171327 + 1 placebo tablet every 3 days.

Reporting group title	Prednisone 5 mg

Reporting group description:

Participants received prednisone 5 mg QD for 8 weeks. From week 9 through 10, the participants received 1 prednisone 5 mg tablet + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 prednisone 5 mg capsule + 1 placebo tablet every 3 days.

Reporting group title	Prednisone 10 mg

Reporting group description:

Participants received prednisone 10 mg QD for 8 weeks. After 8 weeks of treatment, participants were tapered off prednisone dosage. From week 9 through 10, the participants received 1 prednisone 5 mg tablet + 1 placebo tablet every other day. From week 11 through 12, the participants received 1 prednisone 5 mg tablet + 1 placebo tablet every 3 days.

Reporting group title	Placebo

Reporting group description:

Participants received placebo QD until week 12.

Serious adverse events	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	2 / 45 (4.44%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Glioblastoma			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Spinal compression fracture			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Coronary artery disease			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			

subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PF-04171327 15 mg	Prednisone 5 mg	Prednisone 10 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 48 (4.17%)	0 / 45 (0.00%)	2 / 46 (4.35%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Glioblastoma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Spinal compression fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Coronary artery disease			

subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo		

Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 47 (4.26%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Glioblastoma			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Spinal compression fracture			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Coronary artery disease			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			

subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rheumatoid arthritis			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis infective			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	PF-04171327 1 mg	PF-04171327 5 mg	PF-04171327 10 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 45 (44.44%)	18 / 47 (38.30%)	22 / 45 (48.89%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 45 (0.00%)	3 / 47 (6.38%)	0 / 45 (0.00%)
occurrences (all)	0	3	0
Hypotension			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	1 / 45 (2.22%)
occurrences (all)	0	1	1

Varicose vein			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Knee operation			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Tooth extraction			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	1	0	1
Drug ineffective			
subjects affected / exposed	1 / 45 (2.22%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	1	1	0
Face oedema			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Feeling hot			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Local swelling			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	3
Reproductive system and breast disorders			

Polymenorrhoea			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 45 (4.44%)	1 / 47 (2.13%)	4 / 45 (8.89%)
occurrences (all)	2	2	4
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 45 (2.22%)	1 / 47 (2.13%)	1 / 45 (2.22%)
occurrences (all)	1	1	1

Blood bilirubin increased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Blood creatinine decreased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Blood pressure increased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Body temperature increased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Weight increased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Soft tissue injury			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Spinal compression fracture			

subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Extrasystoles			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Tremor			

subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Monocytosis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Astigmatism			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Cataract			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Dry eye			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Presbyopia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	2
Abdominal pain upper			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Food poisoning			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Oral discomfort			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermal cyst			

subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Microalbuminuria			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Nocturia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Goitre			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 45 (2.22%)	1 / 47 (2.13%)	1 / 45 (2.22%)
occurrences (all)	1	1	5
Arthritis			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	3 / 45 (6.67%)
occurrences (all)	1	0	3
Arthropathy			

subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Muscle contracture			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	0	2
Pain in extremity			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	2	0
Pathological fracture			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Rheumatoid arthritis			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Rheumatoid nodule			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Synovial cyst			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Infections and infestations			
Abscess bacterial			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0

Bronchitis			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	1 / 45 (2.22%)
occurrences (all)	0	1	1
Candida infection			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	2	0
Herpes virus infection			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 45 (2.22%)	3 / 47 (6.38%)	3 / 45 (6.67%)
occurrences (all)	1	3	3
Oral herpes			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Pharyngitis bacterial			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	1	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1

Respiratory tract infection viral			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	3 / 45 (6.67%)
occurrences (all)	1	0	3
Urinary tract infection			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Viral rhinitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	1 / 45 (2.22%)
occurrences (all)	0	1	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Dyslipidaemia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			

subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Polydipsia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1

Non-serious adverse events	PF-04171327 15 mg	Prednisone 5 mg	Prednisone 10 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 48 (33.33%)	16 / 45 (35.56%)	19 / 46 (41.30%)
Vascular disorders			
Flushing			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Hot flush			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	1 / 48 (2.08%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	1	2	0
Hypotension			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Varicose vein			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Surgical and medical procedures			
Knee operation			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Tooth extraction			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			

Chest pain			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	2 / 46 (4.35%)
occurrences (all)	1	0	4
Drug ineffective			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Face oedema			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	2 / 46 (4.35%)
occurrences (all)	2	0	2
Reproductive system and breast disorders			
Polymenorrhoea			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Oropharyngeal pain			

subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Respiratory disorder			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Sleep disorder			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	4
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	2 / 46 (4.35%)
occurrences (all)	0	0	2
Blood bilirubin increased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Blood creatinine decreased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			

subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	1 / 46 (2.17%)
occurrences (all)	0	1	1
Body temperature increased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	1 / 48 (2.08%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Soft tissue injury			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Spinal compression fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			

subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	4 / 46 (8.70%)
occurrences (all)	1	0	12
Migraine			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Tremor			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Eosinophilia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Monocytosis			

subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Astigmatism			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Presbyopia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	1 / 48 (2.08%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Aphthous stomatitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			

subjects affected / exposed	2 / 48 (4.17%)	2 / 45 (4.44%)	2 / 46 (4.35%)
occurrences (all)	3	2	2
Food poisoning			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 48 (0.00%)	2 / 45 (4.44%)	0 / 46 (0.00%)
occurrences (all)	0	2	0
Oral discomfort			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Rash			

subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Microalbuminuria			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Nephrolithiasis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Goitre			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	5 / 46 (10.87%)
occurrences (all)	0	1	10
Arthritis			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Arthropathy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	1 / 46 (2.17%)
occurrences (all)	0	1	1
Joint swelling			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	2 / 46 (4.35%)
occurrences (all)	0	1	3
Muscle contracture			

subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	1 / 46 (2.17%)
occurrences (all)	0	2	2
Pathological fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Rheumatoid arthritis			
subjects affected / exposed	2 / 48 (4.17%)	3 / 45 (6.67%)	0 / 46 (0.00%)
occurrences (all)	2	3	0
Rheumatoid nodule			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess bacterial			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Candida infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Gingivitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	1 / 46 (2.17%)
occurrences (all)	0	1	1
Nasopharyngitis			
subjects affected / exposed	2 / 48 (4.17%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	2	0	1
Oral herpes			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Pharyngitis bacterial			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection			
subjects affected / exposed	2 / 48 (4.17%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	2	0	0
Urinary tract infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Viral rhinitis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 45 (2.22%)	1 / 46 (2.17%)
occurrences (all)	0	1	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Dehydration			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Dyslipidaemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed	1 / 48 (2.08%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Polydipsia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 45 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo		
Total subjects affected by non-serious			

adverse events subjects affected / exposed	16 / 47 (34.04%)		
Vascular disorders Flushing subjects affected / exposed occurrences (all)	 0 / 47 (0.00%) 0		
Hot flush subjects affected / exposed occurrences (all)	 0 / 47 (0.00%) 0		
Hypertension subjects affected / exposed occurrences (all)	 0 / 47 (0.00%) 0		
Hypotension subjects affected / exposed occurrences (all)	 0 / 47 (0.00%) 0		
Varicose vein subjects affected / exposed occurrences (all)	 0 / 47 (0.00%) 0		
Surgical and medical procedures Knee operation subjects affected / exposed occurrences (all)	 0 / 47 (0.00%) 0		
Tooth extraction subjects affected / exposed occurrences (all)	 0 / 47 (0.00%) 0		
General disorders and administration site conditions Chest pain subjects affected / exposed occurrences (all)	 0 / 47 (0.00%) 0		
Chills subjects affected / exposed occurrences (all)	 0 / 47 (0.00%) 0		
Drug ineffective subjects affected / exposed occurrences (all)	 1 / 47 (2.13%) 1		
Face oedema			

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Feeling hot			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Local swelling			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Polymenorrhoea			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Productive cough			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Respiratory disorder			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Psychiatric disorders			

Depression			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	3 / 47 (6.38%)		
occurrences (all)	3		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Blood bilirubin increased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Blood creatinine decreased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Blood pressure increased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Body temperature increased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Weight increased			

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Ligament sprain			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Soft tissue injury			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Spinal compression fracture			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Extrasystoles			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	2		
Sinus bradycardia			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	2		
Sinus tachycardia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Headache			

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Presyncope			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Sciatica			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Eosinophilia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Monocytosis			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Neutropenia			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Eye disorders			
Astigmatism			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Cataract			

subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Dry eye			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Presbyopia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Visual impairment			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Aphthous stomatitis			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Food poisoning			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Gastritis			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		

Nausea subjects affected / exposed occurrences (all)	1 / 47 (2.13%) 1		
Oral discomfort subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0		
Vomiting subjects affected / exposed occurrences (all)	1 / 47 (2.13%) 1		
Hepatobiliary disorders Hepatic steatosis subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0		
Skin and subcutaneous tissue disorders Dermal cyst subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0		
Dry skin subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0		
Pruritus subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0		
Rash subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0		
Renal and urinary disorders Microalbuminuria subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0		
Nephrolithiasis subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0		
Nocturia subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0		
Endocrine disorders			

Adrenal insufficiency			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Goitre			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Arthritis			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Arthropathy			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Joint swelling			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Muscle contracture			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Pathological fracture			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Rheumatoid arthritis			

subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Rheumatoid nodule			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Synovial cyst			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Tendonitis			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Abscess bacterial			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Candida infection			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Cystitis			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Gastroenteritis			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Gingivitis			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		
Herpes virus infection			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		
Influenza			
subjects affected / exposed	0 / 47 (0.00%)		
occurrences (all)	0		

Nasopharyngitis				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
Oral herpes				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
Pharyngitis bacterial				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Respiratory tract infection				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Respiratory tract infection viral				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
Upper respiratory tract infection				
subjects affected / exposed	1 / 47 (2.13%)			
occurrences (all)	1			
Urinary tract infection				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Viral infection				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			
Viral rhinitis				
subjects affected / exposed	0 / 47 (0.00%)			
occurrences (all)	0			

Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all) Dehydration subjects affected / exposed occurrences (all) Dyslipidaemia subjects affected / exposed occurrences (all) Hypercholesterolaemia subjects affected / exposed occurrences (all) Hyperuricaemia subjects affected / exposed occurrences (all) Polydipsia subjects affected / exposed occurrences (all)	 0 / 47 (0.00%) 0 0 / 47 (0.00%) 0 1 / 47 (2.13%) 1 0 / 47 (0.00%) 0 0 / 47 (0.00%) 0 0 / 47 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 August 2011	Amendment 1 provided for additional liver test monitoring and follow ups. It also clarified that the Data Monitoring Committee for this study was an IRC.
13 March 2012	Amendment 2 provided for the inclusion of women of childbearing potential and the monitoring of precautionary renal safety parameters. In addition, more details were provided on the planned statistical analysis of study endpoints.
15 June 2012	Amendment 3 was only applicable to study sites in India because of a request by the Drugs Controller General of India, which added an upper age limit for enrollment of subjects of 60 years of age or younger. This requirement was not based on any specific safety concerns; however, it was intended to ensure adequate understanding of protocol specific procedures and demands of study participation such as multiple blood draws, repeated clinic visits, etc. This amendment was to be submitted to the institutional review board (IRB) or IEC responsible for this study at the sites in India via a letter of administration. This letter was to be submitted for information only. No change in the overall conduct of the study based on this letter was to occur.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported