Clinical trial results:
A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of 2 Doses of Tofacitinib (CP-690,550) or Adalimumab in Subjects With Active Psoriatic Arthritis

Summary

EudraCT number	2011-003668-55
Trial protocol	BE CZ ES SK HU DE PL BG
Global end of trial date	18 December 2015

Results information

Result version number	v1 (current)
This version publication date	22 December 2016
First version publication date	22 December 2016

Trial information

Trial identification

Sponsor protocol code	A3921091

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01877668
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, 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	18 December 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 December 2015
Global end of trial reached?	Yes
Global end of trial date	18 December 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objectives of this trail were to compare the efficacy of tofacitinib at doses of 5 mg twice daily (BID) and 10 mg BID versus placebo for the treatment of rheumatological signs and symptoms of psoriatic arthritis (PsA), to compare physical function status, and to compare the safety and tolerability of 2 doses (5 mg BID and 10 mg BID) of tofacitinib versus placebo in participants with active PsA who have had an inadequate response to conventional synthetic disease modifying anti rheumatic drugs.

Protection of trial subjects:

This study was conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonisation Good Clinical Practice Guidelines. In addition, all local regulatory requirements were followed, in particular, those affording greater protection to the safety of trial participants. The final protocol and any amendments were reviewed and approved by the Institutional Review Board(s) and/or Independent Ethics Committee(s) at each of the investigational centres participating in the study.

Background therapy:

Eligible participants remained on a stable dose of 1 conventional synthetic disease-modifying anti-rheumatic drug treatment (ie, methotrexate, sulfasalazine, leflunomide, or others as approved by the Pfizer study clinician) as background therapy.

Evidence for comparator:

Adalimumab was included in a reference arm as an active control. An adalimumab dose of 40 mg subcutaneously administered every 2 weeks is the approved dose for rheumatoid arthritis and psoriasis and was the dose used in this study.

Actual start date of recruitment	20 January 2014
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	Australia: 12
Country: Number of subjects enrolled	Belgium: 3
Country: Number of subjects enrolled	Bulgaria: 28
Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Czech Republic: 18
Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	Germany: 11
Country: Number of subjects enrolled	Hungary: 31
Country: Number of subjects enrolled	Mexico: 15
Country: Number of subjects enrolled	Poland: 160
Country: Number of subjects enrolled	Russian Federation: 39

Country: Number of subjects enrolled	Slovakia: 12
Country: Number of subjects enrolled	Spain: 19
Country: Number of subjects enrolled	Taiwan: 6
Country: Number of subjects enrolled	United Kingdom: 15
Country: Number of subjects enrolled	United States: 47
Worldwide total number of subjects	422
EEA total number of subjects	298

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)	384
From 65 to 84 years	38
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Of 611 participants screened for entry into the study, 422 received treatment.

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	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Tofacitinib, 5 mg, twice daily

Arm description:

Participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo administered every 2 weeks.

Arm type	Experimental
Investigational medicinal product name	Tofacitinib
Investigational medicinal product code	CP-690,550
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Tofacitinib 5 mg administered twice daily (with 1 matching placebo tablet) and subcutaneous placebo every 2 weeks during the placebo controlled period (up to Month 3) and the active extension period (from Month 3 to Month 12).

Arm title	Tofacitinib, 10 mg, twice daily

Arm description:

Participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks.

Arm type	Experimental
Investigational medicinal product name	Tofacitinib
Investigational medicinal product code	CP-690,550
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Tofacitinib 10 mg administered twice daily and subcutaneous placebo every 2 weeks during the placebo controlled period (up to Month 3) and the active extension period (from Month 3 to Month 12).

Arm title	Adalimumab, 40 mg, every 2 weeks

Arm description:

Participants received 2 placebo tablets twice daily and adalimumab, 40 mg, administered subcutaneously every 2 weeks.

Arm type	Active comparator

Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo tablets administered twice daily and subcutaneous adalimumab 40 mg every 2 weeks during the placebo controlled period (up to Month 3) and the active extension period (from Month 3 to Month 12).

Arm title	Placebo/Tofacitinib, 5 mg, twice daily

Arm description:

Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo every 2 weeks.

Arm type	Experimental
Investigational medicinal product name	Tofacitinib
Investigational medicinal product code	CP-690,550
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo tablets administered twice daily and subcutaneous placebo every 2 weeks during the placebo controlled period (up to Month 3) followed by tofacitinib 5 mg administered twice daily (with 1 matching placebo tablet) during the active extension period (from Month 3 to Month 12).

Arm title	Placebo/Tofacitinib, 10 mg, twice daily

Arm description:

Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks.

Arm type	Experimental
Investigational medicinal product name	Tofacitinib
Investigational medicinal product code	CP-690,550
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo tablets administered twice daily and subcutaneous placebo every 2 weeks during the placebo controlled period (up to Month 3) followed by tofacitinib 10 mg administered twice daily during the active extension period (from Month 3 to Month 12).

Number of subjects in period 1	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks
Started	107	104	106
Completed	96	96	94
Not completed	11	8	12
Adverse event, serious fatal	-	-	-
No longer met study criteria	1	-	1
Consent withdrawn by subject	2	-	3
Not specified	1	1	1
Adverse event unrelated to study drug	4	1	2

Lost to follow-up	-	2	1
Adverse event related to study drug	2	2	2
Protocol deviation	1	1	-
Insufficient clinical response	-	1	2

Number of subjects in period 1	Placebo/Tofacitinib, 5 mg, twice daily	Placebo/Tofacitinib, 10 mg, twice daily
Started	52	53
Completed	44	43
Not completed	8	10
Adverse event, serious fatal	1	-
No longer met study criteria	-	-
Consent withdrawn by subject	2	2
Not specified	1	3
Adverse event unrelated to study drug	-	1
Lost to follow-up	-	-
Adverse event related to study drug	2	1
Protocol deviation	-	3
Insufficient clinical response	2	-

Baseline characteristics

Reporting groups	
Reporting group title	Tofacitinib, 5 mg, twice daily
Reporting group description:	
Participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo administered every 2 weeks.	
Reporting group title	Tofacitinib, 10 mg, twice daily
Reporting group description:	
Participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks.	
Reporting group title	Adalimumab, 40 mg, every 2 weeks
Reporting group description:	
Participants received 2 placebo tablets twice daily and adalimumab, 40 mg, administered subcutaneously every 2 weeks.	
Reporting group title	Placebo/Tofacitinib, 5 mg, twice daily
Reporting group description:	
Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo every 2 weeks.	
Reporting group title	Placebo/Tofacitinib, 10 mg, twice daily
Reporting group description:	
Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks.	

Reporting group values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks
Number of subjects	107	104	106
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	95	96	99
From 65-84 years	12	8	7
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	49.4	46.9	47.4
standard deviation	± 12.6	± 12.4	± 11.3
Gender, Male/Female Units: Subjects			
Female	57	62	50
Male	50	42	56

Reporting group values	Placebo/Tofacitinib, 5 mg, twice daily	Placebo/Tofacitinib, 10 mg, twice daily	Total
Number of subjects	52	53	422

Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	50	44	384
From 65-84 years	2	9	38
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	46.1	49.3	
standard deviation	± 10.4	± 13.8	-
Gender, Male/Female Units: Subjects			
Female	28	28	225
Male	24	25	197

Subject analysis sets

Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months.

Reporting group values	Placebo		
Number of subjects	105		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	94		
From 65-84 years	11		
85 years and over	0		
Age Continuous Units: Years			
arithmetic mean	47.7		
standard deviation	± 12.3		
Gender, Male/Female Units: Subjects			
Female	56		
Male	49		

End points

End points reporting groups

Reporting group title	Tofacitinib, 5 mg, twice daily
Reporting group description:	
Participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo administered every 2 weeks.	
Reporting group title	Tofacitinib, 10 mg, twice daily
Reporting group description:	
Participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks.	
Reporting group title	Adalimumab, 40 mg, every 2 weeks
Reporting group description:	
Participants received 2 placebo tablets twice daily and adalimumab, 40 mg, administered subcutaneously every 2 weeks.	
Reporting group title	Placebo/Tofacitinib, 5 mg, twice daily
Reporting group description:	
Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo every 2 weeks.	
Reporting group title	Placebo/Tofacitinib, 10 mg, twice daily
Reporting group description:	
Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks.	
Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months.	

Primary: Percentage of Participants Meeting American College of Rheumatology Response Criteria ≥20% (ACR20): Month 3

End point title	Percentage of Participants Meeting American College of Rheumatology Response Criteria ≥20% (ACR20): Month 3[1]
End point description:	
ACR20 was calculated as a ≥20% improvement from baseline in tender/painful and swollen joint counts and ≥20% improvement from baseline in 3 of the 5 remaining ACR core set measures: patient's global assessment of arthritis, physician's global assessment of arthritis, patient's assessment of arthritis pain, health assessment questionnaire - disability index (HAQ-DI), and C-reactive protein (CRP).	
End point type	Primary
End point timeframe:	
At end of Month 3	

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	107	104	106	105
Units: Percentage or participants				
number (not applicable)	50.47	60.58	51.89	33.33

Statistical analyses

Statistical analysis title	Analysis of ACR20
Comparison groups	Tofacitinib, 5 mg, twice daily v Placebo
Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0102
Method	Large sample approximation
Parameter estimate	Risk difference (RD)
Point estimate	17.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.06
upper limit	30.21
Variability estimate	Standard error of the mean
Dispersion value	6.67

Statistical analysis title	Analysis of ACR20
Comparison groups	Tofacitinib, 10 mg, twice daily v Placebo
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Large sample approximation
Parameter estimate	Risk difference (RD)
Point estimate	27.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.22
upper limit	40.26
Variability estimate	Standard error of the mean
Dispersion value	6.64

Statistical analysis title	Analysis of ACR20

Comparison groups	Adalimumab, 40 mg, every 2 weeks v Placebo
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0055
Method	Large sample approximation
Parameter estimate	Risk difference (RD)
Point estimate	18.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.45
upper limit	31.66
Variability estimate	Standard error of the mean
Dispersion value	6.69

Primary: Change From Baseline in Health Assessment Questionnaire - Disability Index (HAQ-DI) Score: Month 3

End point title	Change From Baseline in Health Assessment Questionnaire - Disability Index (HAQ-DI) Score: Month 3[2]

End point description:

The HAQ-DI assesses the difficulty a participant has had in the past week in 8 domains of daily living activities: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities. Each activity category consists of 2-3 items. For each question, level of difficulty is scored from 0 to 3 with 0=no difficulty, 1=some difficulty, 2=much difficulty, and 3=unable to do. The score for each domain is the maximum (worst) score from the items/questions within the domain. Higher score indicates greater disability.

End point type	Primary

End point timeframe:

From Baseline to Month 3

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	107	104	106	104
Units: Units on a scale				
least squares mean (standard error)	-0.3499 (± 0.04665)	-0.3998 (± 0.04716)	-0.3808 (± 0.04767)	-0.1802 (± 0.05031)

Statistical analyses

Statistical analysis title	Analysis of HAQ-DI
Comparison groups	Tofacitinib, 5 mg, twice daily v Placebo

Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0062
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	-0.1697
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.291
upper limit	-0.0483
Variability estimate	Standard error of the mean
Dispersion value	0.06173

Statistical analysis title	Analysis of HAQ-DI
Comparison groups	Tofacitinib, 10 mg, twice daily v Placebo
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0004
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	-0.2196
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3411
upper limit	-0.098
Variability estimate	Standard error of the mean
Dispersion value	0.06184

Statistical analysis title	Analysis of HAQ-DI
Comparison groups	Adalimumab, 40 mg, every 2 weeks v Placebo
Number of subjects included in analysis	210
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0012
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	-0.2005
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3213
upper limit	-0.0797

Variability estimate	Standard error of the mean
Dispersion value	0.06145

Secondary: Change From Baseline in the Van der Heijdel Modified Total Sharp Score (mTSS) for Psoriatic Arthritis at Month 12

End point title	Change From Baseline in the Van der Heijdel Modified Total Sharp Score (mTSS) for Psoriatic Arthritis at Month 12

End point description:

Assessment of joint damage includes a joint erosion score (range 0-320) and a joint space narrowing (JSN) score (range 0-208). The mTSS is the sum of the erosion and JSN scores (range 0-528). A higher score indicates more severe disease status. If a component score is missing, the mTSS will be missing.

End point type	Secondary

End point timeframe:

From Baseline to Month 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	99	95	48
Units: Units on a scale				
least squares mean (standard error)	0.01 (± 0.067)	-0.01 (± 0.067)	-0.07 (± 0.069)	0 (± 0.094)

End point values	Placebo/Tofacitinib, 10 mg, twice daily			
Subject group type	Reporting group			
Number of subjects analysed	45			
Units: Units on a scale				
least squares mean (standard error)	0.09 (± 0.099)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Progressed Modified Total Sharp Score (mTSS) at Month 12

End point title	Percentage of Participants With Progressed Modified Total Sharp Score (mTSS) at Month 12

End point description:

Assessment of joint damage includes a joint erosion score (range 0-320) and a JSN score (range 0-208). The mTSS is the sum of the erosion and JSN scores (range 0-528). A higher score indicates more severe disease status. If a component score is missing, the mTSS will be missing. Progressor is defined as an increase in mTSS >0.5 from baseline.

End point type	Secondary

End point timeframe:

At Month 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	99	95	48
Units: Percentage of participants				
number (not applicable)	4.08	5.05	2.11	4.17

End point values	Placebo/Tofacitinib, 10 mg, twice daily			
Subject group type	Reporting group			
Number of subjects analysed	45			
Units: Percentage of participants				
number (not applicable)	8.89			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Meeting American College of Rheumatology Response Criteria ≥50% (ACR50) at Week 2 and Months 1, 2, 3, 4, 6, 9, and 12

End point title	Percentage of Participants Meeting American College of Rheumatology Response Criteria ≥50% (ACR50) at Week 2 and Months 1, 2, 3, 4, 6, 9, and 12

End point description:

ACR50 was calculated as a ≥50% improvement from baseline in tender/painful and swollen joint counts and ≥50% improvement from baseline in 3 of the 5 remaining ACR core set measures: patient's global assessment of arthritis, physician's global assessment of arthritis, patient's assessment of arthritis pain, HAQ-DI, and CRP. NA = not applicable, 9999 = results not reported for this group, n=number of responders.

End point type	Secondary

End point timeframe:

At Week 2 and Months 1, 2, 3, 4, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	107	104	106	52
Units: Percentage of participants				
number (not applicable)				
Week 2 (n=7, 7, 5, NA, NA, 1)	6.54	6.73	4.72	9999
Month 1 (n=13, 20,12, NA, NA, 5)	12.15	19.23	11.32	9999
Month 2 (n=23, 34, 24, NA, NA, 8)	21.5	32.69	22.64	9999
Month 3 (n=30, 42, 35, NA, NA, 10)	28.04	40.38	33.02	9999
Month 4 (n=38, 39, 34, 11, 17, NA)	35.51	37.5	32.08	21.15
Month 6 (n=41, 48, 45, 17, 14, NA)	38.32	46.15	42.45	32.69
Month 9 (n=45, 48, 49, 22, 23, NA)	42.06	46.15	46.23	42.31
Month 12 (n=48, 50, 43, 21, 19, NA)	44.86	48.08	40.57	40.38

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	53	105		
Units: Percentage of participants				
number (not applicable)				
Week 2 (n=7, 7, 5, NA, NA, 1)	9999	0.95		
Month 1 (n=13, 20,12, NA, NA, 5)	9999	4.76		
Month 2 (n=23, 34, 24, NA, NA, 8)	9999	7.62		
Month 3 (n=30, 42, 35, NA, NA, 10)	9999	9.52		
Month 4 (n=38, 39, 34, 11, 17, NA)	32.08	9999		
Month 6 (n=41, 48, 45, 17, 14, NA)	26.42	9999		
Month 9 (n=45, 48, 49, 22, 23, NA)	43.4	9999		
Month 12 (n=48, 50, 43, 21, 19, NA)	35.85	9999		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Meeting American College of Rheumatology Response Criteria ≥70% (ACR70) at Week 2 and Months 1, 2, 3, 4, 6, 9, and 12

End point title	Percentage of Participants Meeting American College of Rheumatology Response Criteria ≥70% (ACR70) at Week 2 and Months 1, 2, 3, 4, 6, 9, and 12

End point description:

ACR70 was calculated as a ≥70% improvement from baseline in tender/painful and swollen joint counts and ≥70% improvement from baseline in 3 of the 5 remaining ACR core set measures: patient's global assessment of arthritis, physician's global assessment of arthritis, patient's assessment of arthritis pain, HAQ-DI, and CRP. NA = not applicable, 9999 = results not reported for this group, n=number of responders.

End point type	Secondary

End point timeframe:

At Week 2 and Months 1, 2, 3, 4, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	107	104	106	52
Units: Percentage of participants				
number (not applicable)				
Week 2 (n=0, 3, 1, NA, NA, 0)	0	2.88	0.94	9999
Month 1 (n=5, 8, 4, NA, NA, 1)	4.67	7.69	3.77	9999
Month 2 (n=10, 14, 13, NA, NA, 2)	9.35	13.46	12.26	9999
Month 3 (n=18, 15, 20, NA, NA, 5)	16.82	14.42	18.87	9999
Month 4 (n=24, 23, 21, 7, 8, NA)	22.43	22.12	19.81	13.46
Month 6 (n=19, 33, 32, 10, 7, NA)	17.76	31.73	30.19	19.23
Month 9 (n=21, 31, 30, 15, 12, NA)	19.63	29.81	28.3	28.85
Month 12 (n=25, 32, 31, 12, 12, NA)	23.36	30.77	29.25	23.08

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	53	105		
Units: Percentage of participants				
number (not applicable)				
Week 2 (n=0, 3, 1, NA, NA, 0)	9999	0		
Month 1 (n=5, 8, 4, NA, NA, 1)	9999	0.95		
Month 2 (n=10, 14, 13, NA, NA, 2)	9999	1.9		
Month 3 (n=18, 15, 20, NA, NA, 5)	9999	4.76		
Month 4 (n=24, 23, 21, 7, 8, NA)	15.09	9999		
Month 6 (n=19, 33, 32, 10, 7, NA)	13.21	9999		
Month 9 (n=21, 31, 30, 15, 12, NA)	22.64	9999		
Month 12 (n=25, 32, 31, 12, 12, NA)	22.64	9999		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Meeting American College of Rheumatology Response Criteria ≥20% (ACR20) at Week 2 and Months 1, 2, 4, 6, 9, and 12

End point title	Percentage of Participants Meeting American College of Rheumatology Response Criteria ≥20% (ACR20) at Week 2 and Months 1, 2, 4, 6, 9, and 12

End point description:

ACR20 was calculated as a ≥20% improvement from baseline in tender/painful and swollen joint counts and ≥20% improvement from baseline in 3 of the 5 remaining ACR core set measures: patient's global assessment of arthritis, physician's global assessment of arthritis, patient's assessment of arthritis pain, HAQ-DI, and CRP. NA = not applicable, 9999 = results not reported for this group, n=number of

responders.

End point type	Secondary

End point timeframe:

At Week 2 and Months 1, 2, 4, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	107	104	106	52
Units: Percentage of participants				
number (not applicable)				
Week 2 (n=24, 33, 23, NA, NA, 6)	22.43	31.73	21.7	9999
Month 1 (n=37, 50, 30, NA, NA, 11)	34.58	48.08	28.3	9999
Month 2 (n=47, 57, 62, NA, NA, 28)	43.93	54.81	58.49	9999
Month 4 (n=65, 60, 61, 27, 28, NA)	60.75	57.69	57.55	51.92
Month 6 (n=63, 70, 68, 31, 30, NA)	58.88	67.31	64.15	59.62
Month 9 (n=73, 76, 73, 35, 37, NA)	68.22	73.08	68.87	67.31
Month 12 (n=73, 73, 64, 35, 31, NA)	68.22	70.19	60.38	67.31

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	53	105		
Units: Percentage of participants				
number (not applicable)				
Week 2 (n=24, 33, 23, NA, NA, 6)	9999	5.71		
Month 1 (n=37, 50, 30, NA, NA, 11)	9999	10.48		
Month 2 (n=47, 57, 62, NA, NA, 28)	9999	26.67		
Month 4 (n=65, 60, 61, 27, 28, NA)	52.83	9999		
Month 6 (n=63, 70, 68, 31, 30, NA)	56.6	9999		
Month 9 (n=73, 76, 73, 35, 37, NA)	69.81	9999		
Month 12 (n=73, 73, 64, 35, 31, NA)	58.49	9999		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Health Assessment Questionnaire - Disability Index (HAQ-DI) Score at Week 2 and Months 1, 2, 4, 6, 9, and 12

End point title	Change From Baseline in Health Assessment Questionnaire - Disability Index (HAQ-DI) Score at Week 2 and Months 1, 2, 4, 6, 9, and 12

End point description:

The HAQ-DI assesses the difficulty a participant has had in the past week in 8 domains of daily living

activities: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities. Each activity category consists of 2-3 items. For each question, level of difficulty is scored from 0 to 3 with 0=no difficulty, 1=some difficulty, 2=much difficulty, and 3=unable to do. The score for each domain is the maximum (worst) score from the items/questions within the domain. Higher score indicates greater disability. NA = not applicable, 9999 = results not reported for this group, n=number of responders.

End point type	Secondary

End point timeframe:

From Baseline to Week 2 and Months 1, 2, 4, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	107	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Week 2 (n=106, 102, 103, NA, NA, 102)	-0.1842 (± 0.04131)	-0.2089 (± 0.04208)	-0.2129 (± 0.04246)	9999 (± 9999)
Month 1 (n=105, 103, 104, NA, NA, 103)	-0.2048 (± 0.04363)	-0.2676 (± 0.04426)	-0.3028 (± 0.04465)	9999 (± 9999)
Month 2 (n=104, 104, 104, NA, NA, 102)	-0.2713 (± 0.04626)	-0.4009 (± 0.04678)	-0.3736 (± 0.04719)	9999 (± 9999)
Month 4 (n=102, 100, 102, 50, 50, NA)	-0.4231 (± 0.04982)	-0.4407 (± 0.05039)	-0.3643 (± 0.05069)	-0.285 (± 0.07075)
Month 6 (n=100, 100, 99, 48, 48, NA)	-0.4471 (± 0.05136)	-0.4611 (± 0.05179)	-0.4259 (± 0.05227)	-0.3142 (± 0.07315)
Month 9 (n=99, 96, 96, 47, 45, NA)	-0.5119 (± 0.05038)	-0.4847 (± 0.05096)	-0.4304 (± 0.05143)	-0.3843 (± 0.07185)
Month 12 (n=96, 96, 94, 44, 44, NA)	-0.5391 (± 0.05324)	-0.5104 (± 0.05365)	-0.4478 (± 0.05426)	-0.4104 (± 0.07646)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Week 2 (n=106, 102, 103, NA, NA, 102)	9999 (± 9999)	-0.0837 (± 0.04549)		
Month 1 (n=105, 103, 104, NA, NA, 103)	9999 (± 9999)	-0.1224 (± 0.04755)		
Month 2 (n=104, 104, 104, NA, NA, 102)	9999 (± 9999)	-0.1682 (± 0.04998)		
Month 4 (n=102, 100, 102, 50, 50, NA)	-0.3302 (± 0.07128)	9999 (± 9999)		
Month 6 (n=100, 100, 99, 48, 48, NA)	-0.3841 (± 0.07369)	9999 (± 9999)		
Month 9 (n=99, 96, 96, 47, 45, NA)	-0.4839 (± 0.07276)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	-0.4569 (± 0.07704)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in American College of Rheumatology Response Criteria Components: C-reactive Protein Levels at Month 3

End point title	Change From Baseline in American College of Rheumatology Response Criteria Components: C-reactive Protein Levels at Month 3[3]

End point description:

The test for CRP is a laboratory measurement for evaluation of an acute phase reactant of inflammation through the use of an ultrasensitive assay. A decrease in the level of CRP indicates reduction in inflammation and therefore improvement.

End point type	Secondary

End point timeframe:

From Baseline to end of Month 3

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	101	103	99	101
Units: mg/L				
least squares mean (standard error)	-5.5981 (± 0.80656)	-6.6004 (± 0.80822)	-7.8955 (± 0.82547)	-0.8643 (± 0.86304)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in American College of Rheumatology Response Criteria Components Score: Patient's Assessment of Arthritis Pain at Month 3

End point title	Change From Baseline in American College of Rheumatology Response Criteria Components Score: Patient's Assessment of Arthritis Pain at Month 3[4]

End point description:

Participants assessed the severity of their arthritis pain using a 100-mm visual analog scale (VAS) by placing a mark on the scale between 0 (no pain) and 100 (most severe pain), which corresponded to the magnitude of their pain.

End point type	Secondary

End point timeframe:

From Baseline to end of Month 3

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	103	103	100	102
Units: mm				
least squares mean (standard error)	-21.49 (± 2.325)	-27.1 (± 2.342)	-21.87 (± 2.389)	-10.22 (± 2.499)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in American College of Rheumatology Response Criteria Components Score: Patient's Global Assessment of Arthritis at Month 3

End point title	Change From Baseline in American College of Rheumatology Response Criteria Components Score: Patient's Global Assessment of Arthritis at Month 3[5]

End point description:

Participant answered the following question, "Considering all the ways your arthritis affects you, how are you feeling today?" The participant's response was recorded using a 100 mm VAS.

End point type	Secondary

End point timeframe:

From Baseline to end of Month 3

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	103	103	101	102
Units: mm				
least squares mean (standard error)	-20.08 (± 2.275)	-25.5 (± 2.291)	-21.47 (± 2.328)	-11.4 (± 2.439)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in American College of Rheumatology Response Criteria Components Score: Physician's Global Assessment of Arthritis at Month 3

End point title	Change From Baseline in American College of Rheumatology Response Criteria Components Score: Physician's Global Assessment of Arthritis at Month 3[6]

End point description:

The blinded investigator or qualified assessor assessed how the participant's overall arthritis appeared 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.

End point type	Secondary

End point timeframe:

From Baseline to end of Month 3

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	103	101	101	102
Units: mm				
least squares mean (standard error)	-27.44 (± 1.998)	-33.74 (± 2.021)	-29.02 (± 2.043)	-22.26 (± 2.121)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in American College of Rheumatology Response Criteria Components Score: Swollen Joint Count at Month 3

End point title	Change From Baseline in American College of Rheumatology Response Criteria Components Score: Swollen Joint Count at Month 3[7]

End point description:

Swollen joint counts are considered the most specific quantitative clinical measure used to assess the status of participants with inflammatory types of arthritis. Sixty six (66) joints were assesed by a blinded assessor to determine the number of joints that were considered swelling.

End point type	Secondary

End point timeframe:

From Baseline to end of Month 3

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	103	103	101	102
Units: Joints				
least squares mean (standard error)	-6.5 (± 0.58)	-7.6 (± 0.58)	-6.5 (± 0.59)	-4.8 (± 0.62)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in American College of Rheumatology Response Criteria Components Score: Tender/Painful Joint Count at Month 3

End point title	Change From Baseline in American College of Rheumatology Response Criteria Components Score: Tender/Painful Joint Count at Month 3[8]

End point description:

Tender/painful joint counts are considered the most specific quantitative clinical measure used to assess the status of participants with inflammatory types of arthritis. Sixty eight (68) joints were assessed by a blinded assessor to determine the number of joints that were considered tender or painful.

End point type	Secondary

End point timeframe:

From Baseline to end of Month 3

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	103	103	101	102
Units: Joints				
least squares mean (standard error)	-8.7 (± 1.04)	-11 (± 1.05)	-7.6 (± 1.07)	-6.9 (± 1.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Meeting Psoriatic Arthritis Response Criteria (PsARC) at Week 2 and Months 1, 2, 3, 4, 6, 9, and 12

End point title	Percentage of Participants Meeting Psoriatic Arthritis Response Criteria (PsARC) at Week 2 and Months 1, 2, 3, 4, 6, 9, and 12

End point description:

The PsARC covers 4 measures: Tender joint count, swollen joint count, the Physician's Global Assessment of Arthritis, and the Patient's Global Assessment of Arthritis. The PsARC response is defined as improvement in 2 of 4 items, 1 of which must be joint pain or swelling, without worsening in any measure. Improvement criteria: ≥20% improvement in Physician's Global Assessment of Arthritis;

≥20% improvement in Patient's Global Assessment of Arthritis; ≥30% improvement in tender joint count; and ≥30% improvement in swollen joint count. NA = not applicable, 9999 = results not reported for this group, n=number of responders.

End point type	Secondary

End point timeframe:

At Week 2 and Months 1, 2, 3, 4, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	107	104	106	52
Units: Percentage of participants				
number (not applicable)				
Week 2 (n=34, 42, 23, NA, NA, 10)	31.78	40.38	21.7	9999
Month 1 (n=45, 51, 43, NA, NA, 23)	42.06	49.04	40.57	9999
Month 2 (n=54, 69, 62, NA, NA, 36)	50.47	66.35	58.49	9999
Month 3 (n=55, 73, 65, NA, NA, 47)	51.4	70.19	61.32	9999
Month 4 (n=68, 68, 71, 32, 30, NA)	63.55	65.38	66.98	61.54
Month 6 (n=61, 75, 71, 35, 35, NA)	57.01	72.12	66.98	67.31
Month 9 (n=75, 73, 71, 36, 37, NA)	70.09	70.19	66.98	69.23
Month 12 (n=69, 76, 69, 39, 33, NA)	64.49	73.08	65.09	75

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	53	105		
Units: Percentage of participants				
number (not applicable)				
Week 2 (n=34, 42, 23, NA, NA, 10)	9999	9.52		
Month 1 (n=45, 51, 43, NA, NA, 23)	9999	21.9		
Month 2 (n=54, 69, 62, NA, NA, 36)	9999	34.29		
Month 3 (n=55, 73, 65, NA, NA, 47)	9999	44.76		
Month 4 (n=68, 68, 71, 32, 30, NA)	56.6	9999		
Month 6 (n=61, 75, 71, 35, 35, NA)	66.04	9999		
Month 9 (n=75, 73, 71, 36, 37, NA)	69.81	9999		
Month 12 (n=69, 76, 69, 39, 33, NA)	62.26	9999		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Physician's Global Assessment of Psoriasis (PGA-PsO) Response at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in Physician's Global Assessment of

	Psoriasis (PGA-PsO) Response at Months 1, 3, 6, 9, and 12

End point description:

The PGA-PsO is scored on a 5-point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling are rated separately over the whole body according to a 5-point severity scale, scored as 0=none; 1, 2, 3, or 4=most severe. The severity rating scores are summed and the average taken; the total average is rounded to the nearest whole number score to determine the PGA-PsO. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	98	102	50
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=100, 96, 100, NA, NA, 99)	-0.7 (± 0.07)	-0.8 (± 0.08)	-0.5 (± 0.08)	9999 (± 9999)
Month 3 (n=98, 97, 98, NA, NA, 98)	-1 (± 0.08)	-1.2 (± 0.08)	-1 (± 0.09)	9999 (± 9999)
Month 6 (n=96, 94, 96, 46, 46, NA)	-0.9 (± 0.09)	-1.3 (± 0.09)	-1.2 (± 0.09)	-0.7 (± 0.12)
Month 9 (n=95, 91, 94, 45, 44, NA)	-1 (± 0.09)	-1.5 (± 0.09)	-1.2 (± 0.09)	-0.7 (± 0.12)
Month 12 (n=91, 90, 92, 41, 43, NA)	-1.2 (± 0.09)	-1.5 (± 0.09)	-1.2 (± 0.09)	-0.9 (± 0.13)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	50	100		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=100, 96, 100, NA, NA, 99)	9999 (± 9999)	-0.2 (± 0.08)		
Month 3 (n=98, 97, 98, NA, NA, 98)	9999 (± 9999)	-0.4 (± 0.09)		
Month 6 (n=96, 94, 96, 46, 46, NA)	-0.9 (± 0.13)	9999 (± 9999)		
Month 9 (n=95, 91, 94, 45, 44, NA)	-1.3 (± 0.13)	9999 (± 9999)		
Month 12 (n=91, 90, 92, 41, 43, NA)	-1.3 (± 0.13)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Psoriasis Area and Severity Index 75 (PASI75) Response at Months 1, 3, 6, 9, and 12

End point title	Percentage of Participants With Psoriasis Area and Severity Index 75 (PASI75) Response at Months 1, 3, 6, 9, and 12

End point description:

PASI determines psoriasis severity based on lesion severity & percentage of body surface area (BSA) affected. Lesion severity is assessed for erythema, induration & scaling; each evaluated separately for head & neck, upper limbs, trunk & lower limbs then rated for each body area on a 5 point scale: 0=no involvement; 1=slight; 2=moderate; 3=marked; 4=very marked. BSA involvement is the extent (%) of body area affected by psoriasis & is given a numerical score: 0=no involvement; 1=0-9%; 2=10-29%; 3=30-49%; 4=50-69%; 5=70-89%; 6=90-100%. In each area, the sum of the severity rating scores is multiplied by the score representing the percentage of this area involved by psoriasis, multiplied by a weighting factor (head 0.1; upper limbs 0.2; trunk 0.3; lower limbs 0.4). The sum of the numbers obtained for each of the 4 body areas is the PASI. PASI75 is defined as a 75% reduction from baseline in PASI. NA = not applicable, 9999 = results not reported for this group, n=number of responders.

End point type	Secondary

End point timeframe:

At Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	70	77	42
Units: Percentage of participants				
number (not applicable)				
Month 1 (n=19, 19, 11, NA, NA, 4)	23.17	27.14	14.29	9999
Month 3 (n=35, 31, 30, NA, NA, 12)	42.68	44.29	38.96	9999
Month 6 (n=38, 42, 42, 12, 17, NA)	46.34	60	54.55	28.57
Month 9 (n=36, 48, 45, 14, 20, NA)	43.9	68.57	58.44	33.33
Month 12 (n=46, 47, 43, 15, 21, NA)	56.1	67.14	55.84	35.71

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	40	82		
Units: Percentage of participants				
number (not applicable)				
Month 1 (n=19, 19, 11, NA, NA, 4)	9999	4.88		
Month 3 (n=35, 31, 30, NA, NA, 12)	9999	14.63		
Month 6 (n=38, 42, 42, 12, 17, NA)	42.5	9999		
Month 9 (n=36, 48, 45, 14, 20, NA)	50	9999		
Month 12 (n=46, 47, 43, 15, 21, NA)	52.5	9999		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Dactylitis Severity Score (DSS) at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in Dactylitis Severity Score (DSS) at

	Months 1, 3, 6, 9, and 12

End point description:

Dactylitis is characterized by swelling of the entire finger or toe. The DSS is a function of finger circumference and tenderness, assessed and summed across all dactylitic digits. The severity of dactylitis is scored on a scale of 0–3, where 0=no tenderness and 3=extreme tenderness in each digit of the hands and feet. The range of total dactylitis scores for a patient is 0-60. Higher score indicates greater degree of tenderness. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	60	58	29
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=58, 59, 56, NA, NA, 56)	-1.8 (± 0.91)	-3.1 (± 0.87)	-2.1 (± 0.93)	9999 (± 9999)
Month 3 (n=58, 60 , 56, NA, NA, 55)	-3.5 (± 0.95)	-5.5 (± 0.91)	-4 (± 0.97)	9999 (± 9999)
Month 6 (n=58, 59, 55, 28, 25, NA)	-5.2 (± 1.01)	-6.4 (± 0.99)	-5.4 (± 1.03)	-5.9 (± 1.45)
Month 9 (n=57, 59, 53, 27, 25, NA)	-7 (± 0.6)	-7.2 (± 0.58)	-6.5 (± 0.63)	-5.3 (± 0.87)
Month 12 (n=54, 58, 52, 26, 24, NA)	-7.4 (± 0.65)	-7.5 (± 0.62)	-6.1 (± 0.67)	-6.7 (± 0.93)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	28	57		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=58, 59, 56, NA, NA, 56)	9999 (± 9999)	0.6 (± 1.02)		
Month 3 (n=58, 60 , 56, NA, NA, 55)	9999 (± 9999)	-2 (± 1.06)		
Month 6 (n=58, 59, 55, 28, 25, NA)	-5.2 (± 1.5)	9999 (± 9999)		
Month 9 (n=57, 59, 53, 27, 25, NA)	-7.9 (± 0.89)	9999 (± 9999)		
Month 12 (n=54, 58, 52, 26, 24, NA)	-7.7 (± 0.96)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in the Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index at Months 1, 3, 6, 9, and 12

End point description:

The SPARCC Enthesitis Index identifies the presence or absence of tenderness at 16 enthesial sites, including the bilateral Achilles tendons, plantar fascia insertion at the calcaneus, patellar tendon insertion at the base of the patella, quadriceps insertion into the superior border of the patella, supraspinatus insertion into the greater tuberosity of the humerus, and medial and lateral epicondyles. On examination, tenderness is recorded as present (1) or absent (0) for each of the 16 sites, with an overall total score ranging from 0 to 16. Higher score indicates a greater number of sites that are affected by enthesitis. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	80	81	82	38
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=79, 80, 80, NA, NA, 78)	-0.83 (± 0.317)	-1.27 (± 0.321)	-0.95 (± 0.336)	9999 (± 9999)
Month 3 (n=77, 79, 79, NA, NA, 78)	-1.84 (± 0.363)	-2.41 (± 0.364)	-1.9 (± 0.375)	9999 (± 9999)
Month 6 (n=76, 78, 76, 33, 39, NA)	-2.4 (± 0.34)	-2.6 (± 0.34)	-2.3 (± 0.35)	-2.4 (± 0.5)
Month 9 (n=75, 75, 73, 34, 37, NA)	-2.9 (± 0.31)	-2.6 (± 0.32)	-3 (± 0.33)	-2.8 (± 0.46)
Month 12 (n=72, 73, 72, 31, 37, NA)	-3.2 (± 0.33)	-3.1 (± 0.33)	-2.8 (± 0.35)	-2.5 (± 0.49)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	41	79		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=79, 80, 80, NA, NA, 78)	9999 (± 9999)	-0.58 (± 0.355)		
Month 3 (n=77, 79, 79, NA, NA, 78)	9999 (± 9999)	-1.17 (± 0.393)		
Month 6 (n=76, 78, 76, 33, 39, NA)	-2.5 (± 0.48)	9999 (± 9999)		
Month 9 (n=75, 75, 73, 34, 37, NA)	-3.2 (± 0.44)	9999 (± 9999)		
Month 12 (n=72, 73, 72, 31, 37, NA)	-3.2 (± 0.46)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Leeds Enthesitis Index (LEI) at Months 1,

3, 6, 9, and 12

End point title	Change From Baseline in the Leeds Enthesitis Index (LEI) at Months 1, 3, 6, 9, and 12

End point description:

Enthesitis is inflammation in the tendon, ligament, and joint capsule fiber insertion into bone. The LEI assesses enthesitis in 6 sites. Tenderness is recorded as either present (1) or absent (0) for each of the 6 sites, for an total score of 0–6. Higher score indicates a greater number of sites affected by enthesis. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	74	64	76	31
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=74, 63, 75, NA, NA, 65)	-0.41 (± 0.192)	-0.57 (± 0.213)	-0.42 (± 0.203)	9999 (± 9999)
Month 3 (n=70, 63, 73, NA, NA, 63)	-0.82 (± 0.221)	-1.46 (± 0.24)	-1.1 (± 0.228)	9999 (± 9999)
Month 6 (n=72, 61, 71, 27, 31, NA)	-1.3 (± 0.21)	-1.2 (± 0.23)	-1.3 (± 0.22)	-1 (± 0.32)
Month 9 (n=70, 58, 68, 27, 29, NA)	-1.4 (± 0.2)	-1.3 (± 0.23)	-1.5 (± 0.21)	-1.4 (± 0.31)
Month 12 (n=67, 56, 67, 24, 29, NA)	-1.7 (± 0.19)	-1.6 (± 0.21)	-1.6 (± 0.2)	-1.4 (± 0.3)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	34	65		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=74, 63, 75, NA, NA, 65)	9999 (± 9999)	-0.26 (± 0.219)		
Month 3 (n=70, 63, 73, NA, NA, 63)	9999 (± 9999)	-0.43 (± 0.246)		
Month 6 (n=72, 61, 71, 27, 31, NA)	-1.3 (± 0.3)	9999 (± 9999)		
Month 9 (n=70, 58, 68, 27, 29, NA)	-1.7 (± 0.3)	9999 (± 9999)		
Month 12 (n=67, 56, 67, 24, 29, NA)	-1.9 (± 0.28)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2

(SF-36v2) Acute, Physical Component Summary Score at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2) Acute, Physical Component Summary Score at Months 1, 3, 6, 9, and 12

End point description:

The SF-36v2 acute is a 36-item measure that evaluates 8 domains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. The health domains are aggregated into two summary scores known as the physical component summary score and the mental component summary score. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	3.39 (± 0.638)	4.66 (± 0.645)	4 (± 0.655)	9999 (± 9999)
Month 3 (n=102, 103,100, NA, NA, 102)	5.51 (± 0.733)	5.69 (± 0.735)	6.23 (± 0.748)	9999 (± 9999)
Month 6 (n=100, 100, 98, 48, 48, NA)	6.72 (± 0.773)	6.7 (± 0.777)	6.26 (± 0.788)	5.86 (± 1.101)
Month 9 (n=99, 97, 95, 47, 46, NA)	7.52 (± 0.781)	7.21 (± 0.787)	6.91 (± 0.798)	6.16 (± 1.115)
Month 12 (n=96, 96, 94, 44, 43, NA)	7.61 (± 0.806)	7.67 (± 0.81)	6.74 (± 0.822)	5.82 (± 1.16)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	9999 (± 9999)	1.54 (± 0.7)		
Month 3 (n=102, 103,100, NA, NA, 102)	9999 (± 9999)	2.68 (± 0.785)		
Month 6 (n=100, 100, 98, 48, 48, NA)	6.07 (± 1.112)	9999 (± 9999)		
Month 9 (n=99, 97, 95, 47, 46, NA)	7.15 (± 1.13)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 43, NA)	5.72 (± 1.177)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute, Mental Component Summary Score at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute, Mental Component Summary Score at Months 1, 3, 6, 9, and 12

End point description:

The SF-36v2 acute is a 36-item measure that evaluates 8 domains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. The health domains are aggregated into two summary scores known as the physical component summary score and the mental component summary score. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104,NA, NA, 103)	4.12 (± 0.841)	3.63 (± 0.849)	2.13 (± 0.871)	9999 (± 9999)
Month 3 (n=102, 103,100, NA, NA, 102)	4.35 (± 0.909)	4.2 (± 0.909)	3.13 (± 0.938)	9999 (± 9999)
Month 6 (n=100, 100, 98, 48, 48, NA)	5.7 (± 0.927)	5.51 (± 0.93)	4.58 (± 0.955)	4.5 (± 1.319)
Month 9 (n=99, 97, 95, 47, 46, NA)	5.07 (± 0.974)	6.2 (± 0.982)	3.68 (± 1.005)	4.61 (± 1.391)
Month 12 (n=96, 96, 94, 44, 43, NA)	4.82 (± 1.012)	6.26 (± 1.016)	4.81 (± 1.039)	4.51 (± 1.455)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104,NA, NA, 103)	9999 (± 9999)	3.19 (± 0.917)		
Month 3 (n=102, 103,100, NA, NA, 102)	9999 (± 9999)	3.27 (± 0.976)		
Month 6 (n=100, 100, 98, 48, 48, NA)	3.62 (± 1.331)	9999 (± 9999)		
Month 9 (n=99, 97, 95, 47, 46, NA)	6.03 (± 1.409)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 43, NA)	4.43 (± 1.474)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Physical Functioning Domain at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in the Short-Form-36 Health Survey

	Version 2 (SF-36v2), Acute Components: Physical Functioning Domain at Months 1, 3, 6, 9, and 12

End point description:

The 10 items of the physical functioning scale represent levels and kinds of limitations between the extremes of physical activities, including lifting and carrying groceries; climbing stairs; bending, kneeling, or stooping; walking moderate distances; self-care limitations. The physical functioning items capture both the presence and extent of physical limitations using a 3-level response continuum. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	2.43 (± 0.768)	3.89 (± 0.776)	2.81 (± 0.787)	9999 (± 9999)
Month 3 (n=102, 103,101, NA, NA, 102)	5.17 (± 0.846)	5.23 (± 0.848)	5.22 (± 0.862)	9999 (± 9999)
Month 6 (n=100, 100, 99, 48, 48, NA)	7.02 (± 0.897)	6.15 (± 0.9)	6.36 (± 0.912)	5.22 (± 1.276)
Month 9 (n=99, 97, 96, 47, 46, NA)	7.43 (± 0.902)	6.67 (± 0.909)	7.01 (± 0.921)	5.69 (± 1.285)
Month 12 (n=96, 96, 94, 44, 44, NA)	7.67 (± 0.899)	7.11 (± 0.903)	6.81 (± 0.917)	6.49 (± 1.292)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	9999 (± 9999)	1.1 (± 0.84)		
Month 3 (n=102, 103,101, NA, NA, 102)	9999 (± 9999)	2.06 (± 0.91)		
Month 6 (n=100, 100, 99, 48, 48, NA)	5.22 (± 1.291)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	6.25 (± 1.306)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	4.77 (± 1.308)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Role-Physical Domain at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Role-Physical Domain at Months 1, 3, 6, 9, and 12

End point description:

The 4-item role-physical scale covers an array of physical health-related role limitations, including: a) limitations in the kind of work or other usual activities; b) reductions in the amount of time spent on work or other usual activities; c) difficulty performing work or other usual activities; and d) accomplishing less. Items in the role-physical scale are answered on a 5-point scale. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	4.05 (± 0.751)	3.72 (± 0.759)	4.09 (± 0.77)	9999 (± 9999)
Month 3 (n=102, 103, 100, NA, NA, 102)	4.45 (± 0.801)	4.79 (± 0.803)	5.21 (± 0.82)	9999 (± 9999)
Month 6 (n=100, 100, 99, 48, 48, NA)	6.02 (± 0.824)	5.21 (± 0.828)	5.48 (± 0.84)	4.97 (± 1.172)
Month 9 (n=99, 97, 96, 47, 46, NA)	6.24 (± 0.853)	6.56 (± 0.861)	5.79 (± 0.872)	4.68 (± 1.217)
Month 12 (n=96, 96, 94, 44, 44, NA)	6.21 (± 0.888)	7.11 (± 0.892)	6.37 (± 0.906)	2.98 (± 1.279)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	9999 (± 9999)	1.98 (± 0.82)		
Month 3 (n=102, 103, 100, NA, NA, 102)	9999 (± 9999)	3.63 (± 0.862)		
Month 6 (n=100, 100, 99, 48, 48, NA)	5.03 (± 1.185)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	6.7 (± 1.234)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	5.03 (± 1.291)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Bodily Pain Domain at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Bodily Pain Domain at Months 1, 3, 6, 9, and 12

End point description:

The bodily pain scale comprises of 2 items pertaining to the intensity of bodily pain and extent of interference with normal work activities. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	5.53 (± 0.777)	7.16 (± 0.786)	6.42 (± 0.802)	9999 (± 9999)
Month 3 (n=102, 103, 101, NA, NA, 102)	7.75 (± 0.838)	8.05 (± 0.84)	7.52 (± 0.859)	9999 (± 9999)
Month 6 (n=100, 100, 99, 48, 48, NA)	7.76 (± 0.985)	10.65 (± 0.989)	7.76 (± 1.004)	8.55 (± 1.405)
Month 9 (n=99, 97, 96, 47, 46, NA)	9.03 (± 0.953)	10.13 (± 0.96)	8.59 (± 0.977)	8.46 (± 1.362)
Month 12 (n=96, 96, 94, 44, 43, NA)	9.15 (± 0.961)	11.38 (± 0.965)	9.18 (± 0.984)	8.59 (± 1.384)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	9999 (± 9999)	3.44 (± 0.851)		
Month 3 (n=102, 103, 101, NA, NA, 102)	9999 (± 9999)	3.77 (± 0.903)		
Month 6 (n=100, 100, 99, 48, 48, NA)	8.98 (± 1.425)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	10.81 (± 1.389)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 43, NA)	8.61 (± 1.413)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: General Health Domain at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: General Health Domain at Months 1, 3, 6, 9, and 12

End point description:

The general health scale consists of 5 items including a rating of health and 4 items addressing the respondent's view and expectations of his or her health. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	3.29 (± 0.61)	3.87 (± 0.616)	1.96 (± 0.625)	9999 (± 9999)
Month 3 (n=102, 103,101, NA, NA, 102)	4.09 (± 0.7)	3.95 (± 0.701)	4.73 (± 0.713)	9999 (± 9999)
Month 6 (n=100, 100, 99, 48, 48, NA)	5.96 (± 0.72)	4.12 (± 0.722)	4.81 (± 0.733)	4.39 (± 1.022)
Month 9 (n=99, 97, 96, 47, 46, NA)	5.93 (± 0.773)	5.18 (± 0.778)	4.09 (± 0.788)	4.72 (± 1.102)
Month 12 (n=96, 96, 94, 44, 44, NA)	5.7 (± 0.811)	4.63 (± 0.815)	4.21 (± 0.825)	4.5 (± 1.164)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	9999 (± 9999)	2.15 (± 0.666)		
Month 3 (n=102, 103,101, NA, NA, 102)	9999 (± 9999)	2.64 (± 0.748)		
Month 6 (n=100, 100, 99, 48, 48, NA)	3.92 (± 1.033)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	4.85 (± 1.117)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	4.12 (± 1.175)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Vitality Domain at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Vitality Domain at Months 1, 3, 6, 9, and 12

End point description:

This 4-item measure of vitality captures a broad range of subjective evaluations of well-being from

feelings of tiredness and being worn out to feeling full of energy all or most of the time. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	3.64 (± 0.802)	4.59 (± 0.806)	2.42 (± 0.826)	9999 (± 9999)
Month 3 (n=102, 103, 101, NA, NA, 102)	5.5 (± 0.889)	5.9 (± 0.887)	4.93 (± 0.909)	9999 (± 9999)
Month 6 (n=100, 100, 99, 48, 48, NA)	6.81 (± 0.969)	7.41 (± 0.97)	5.05 (± 0.989)	5.34 (± 1.378)
Month 9 (n=99, 97, 96, 47, 46, NA)	6.09 (± 1.017)	7.82 (± 1.023)	5.27 (± 1.041)	6.61 (± 1.451)
Month 12 (n=96, 96, 94, 44, 44, NA)	7.01 (± 1.022)	7.02 (± 1.024)	5.12 (± 1.043)	5.62 (± 1.465)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	9999 (± 9999)	2.16 (± 0.877)		
Month 3 (n=102, 103, 101, NA, NA, 102)	9999 (± 9999)	3.05 (± 0.954)		
Month 6 (n=100, 100, 99, 48, 48, NA)	4.62 (± 1.394)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	6.39 (± 1.472)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	5.15 (± 1.481)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Social Functioning Domain at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Social Functioning Domain at Months 1, 3, 6, 9, and 12

End point description:

This 2-item scale assesses health-related effects on quantity and quality of social activities. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	4.51 (± 0.827)	4.46 (± 0.838)	3.34 (± 0.852)	9999 (± 9999)
Month 3 (n=102, 103, 101, NA, NA, 102)	5.95 (± 0.897)	5.22 (± 0.898)	5.26 (± 0.918)	9999 (± 9999)
Month 6 (n=100, 100, 99, 48, 48, NA)	6.97 (± 0.955)	7.08 (± 0.959)	7.1 (± 0.975)	5.44 (± 1.362)
Month 9 (n=99, 97, 96, 47, 46, NA)	7.66 (± 0.947)	7.74 (± 0.957)	5.69 (± 0.972)	5.95 (± 1.355)
Month 12 (n=96, 96, 94, 44, 44, NA)	6.13 (± 0.989)	8.42 (± 0.995)	6.32 (± 1.012)	6.19 (± 1.427)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	9999 (± 9999)	2.96 (± 0.901)		
Month 3 (n=102, 103, 101, NA, NA, 102)	9999 (± 9999)	3.63 (± 0.961)		
Month 6 (n=100, 100, 99, 48, 48, NA)	6.05 (± 1.373)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	8.93 (± 1.373)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	6.41 (± 1.445)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Role-Emotional Domain at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Role-Emotional Domain at Months 1, 3, 6, 9, and 12

End point description:

The 3-item role-emotional scale assesses mental health-related role limitations in terms of a) time spent in work or other usual activities; b) amount of work or activities accomplished; c) care with which work or other activities were performed. All 3 items are answered on a 5-point scale. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	4.77 (± 0.96)	3.87 (± 0.971)	2.93 (± 0.991)	9999 (± 9999)
Month 3 (n=102, 103, 100, NA, NA, 102)	4.21 (± 1.01)	4.82 (± 1.011)	3.35 (± 1.04)	9999 (± 9999)
Month 6 (n=100, 100, 98, 48, 48, NA)	5.67 (± 1.024)	4.68 (± 1.027)	4.77 (± 1.051)	6.34 (± 1.458)
Month 9 (n=99, 97, 95, 47, 46, NA)	5.13 (± 1.021)	6.13 (± 1.03)	4.87 (± 1.052)	5.89 (± 1.456)
Month 12 (n=96, 96, 94, 44, 44, NA)	5.15 (± 1.048)	6.73 (± 1.053)	6.03 (± 1.075)	4.77 (± 1.509)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103,104, NA, NA, 103)	9999 (± 9999)	4.52 (± 1.042)		
Month 3 (n=102, 103, 100, NA, NA, 102)	9999 (± 9999)	3.68 (± 1.083)		
Month 6 (n=100, 100, 98, 48, 48, NA)	4.56 (± 1.473)	9999 (± 9999)		
Month 9 (n=99, 97, 95, 47, 46, NA)	6.52 (± 1.478)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	4.94 (± 1.525)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Mental Health Domain at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Mental Health Domain at Months 1, 3, 6, 9, and 12

End point description:

The 5-item mental health scale includes 1 or more items from each of 4 major mental health dimensions: anxiety, depression, loss of behavioural/emotional control, and psychological well-being. All items are answered on a 5-point scale. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103, 104, NA, NA, 103)	3.32 (± 0.867)	3.87 (± 0.874)	2.79 (± 0.895)	9999 (± 9999)
Month 3 (n=102, 103, 101, NA, NA, 102)	4.45 (± 0.934)	4.23 (± 0.932)	3.95 (± 0.956)	9999 (± 9999)
Month 6 (n=100, 100, 99, 48, 48, NA)	6.11 (± 0.951)	6.38 (± 0.953)	5.35 (± 0.974)	3.7 (± 1.354)
Month 9 (n=99, 97, 96, 47, 46, NA)	5.79 (± 1.022)	6.43 (± 1.028)	4.62 (± 1.048)	3.57 (± 1.461)
Month 12 (n=96, 96, 94, 44, 44, NA)	5.86 (± 1.019)	6.58 (± 1.022)	5.86 (± 1.044)	4.72 (± 1.467)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103, 104, NA, NA, 103)	9999 (± 9999)	1.57 (± 0.952)		
Month 3 (n=102, 103, 101, NA, NA, 102)	9999 (± 9999)	2.62 (± 1.009)		
Month 6 (n=100, 100, 99, 48, 48, NA)	3.41 (± 1.372)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	5.45 (± 1.483)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	4.48 (± 1.483)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Score on EuroQol-5 Dimension Health State Profile (EQ-5D) and Change in Patient's Self-rated Health on a Vertical Visual Analogue Scale (VAS) Recorded on the EQ-5D Questionnaire (EQ-VAS): Mobility at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in Score on EuroQol-5 Dimension Health State Profile (EQ-5D) and Change in Patient's Self-rated Health on a Vertical Visual Analogue Scale (VAS) Recorded on the EQ-5D Questionnaire (EQ-VAS): Mobility at Months 1, 3, 6, 9, and 12

End point description:

The EQ-5D is a descriptive system of health-related quality of life states consisting of 5 dimensions

(mobility, self-care, usual activities, pain/discomfort, anxiety/depression) each of which can take 1 of 3 responses. The responses record 3 levels of severity (no problems/some or moderate problems/extreme problems) within a particular EQ-5D dimension. Standard vertical 0 to 100 mm visual analogue scale (similar to a thermometer) for recording an individual's rating for their current health-related quality of life state. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103, 104, NA, NA, 103)	-0.07 (± 0.042)	-0.19 (± 0.043)	-0.15 (± 0.043)	9999 (± 9999)
Month 3 (n=101, 103, 101, NA, NA, 102)	-0.28 (± 0.047)	-0.27 (± 0.047)	-0.29 (± 0.048)	9999 (± 9999)
Month 6 (n=100, 100, 99, 48, 48, NA)	-0.3 (± 0.05)	-0.3 (± 0.05)	-0.2 (± 0.05)	-0.3 (± 0.07)
Month 9 (n=99, 97, 96, 47, 46, NA)	-0.3 (± 0.05)	-0.3 (± 0.05)	-0.3 (± 0.05)	-0.3 (± 0.07)
Month 12 (n=96, 96, 94, 44,44, NA)	-0.3 (± 0.05)	-0.3 (± 0.05)	-0.3 (± 0.05)	-0.4 (± 0.07)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103, 104, NA, NA, 103)	9999 (± 9999)	-0.1 (± 0.046)		
Month 3 (n=101, 103, 101, NA, NA, 102)	9999 (± 9999)	-0.11 (± 0.05)		
Month 6 (n=100, 100, 99, 48, 48, NA)	-0.2 (± 0.07)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	-0.3 (± 0.07)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44,44, NA)	-0.3 (± 0.07)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Self-care at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in Score on EQ-5D and Change in

	Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Self-care at Months 1, 3, 6, 9, and 12

End point description:

The EQ-5D is a descriptive system of health-related quality of life states consisting of 5 dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) each of which can take 1 of 3 responses. The responses record 3 levels of severity (no problems/some or moderate problems/extreme problems) within a particular EQ-5D dimension. Standard vertical 0 to 100 mm visual analogue scale (similar to a thermometer) for recording an individual's rating for their current health-related quality of life state. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	103	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 102, 104, NA, NA, 103)	-0.11 (± 0.046)	-0.16 (± 0.047)	-0.16 (± 0.047)	9999 (± 9999)
Month 3 (n=101, 102, 101, NA, NA, 102)	-0.19 (± 0.047)	-0.11 (± 0.047)	-0.18 (± 0.048)	9999 (± 9999)
Month 6 (n=100, 99, 99, 48, 48, NA)	-0.2 (± 0.04)	-0.3 (± 0.05)	-0.2 (± 0.05)	-0.2 (± 0.06)
Month 9 (n=99, 97, 96, 47, 46, NA)	-0.2 (± 0.05)	-0.2 (± 0.05)	-0.3 (± 0.05)	-0.2 (± 0.06)
Month 12 (n=96, 96, 94, 44, 44, NA)	-0.2 (± 0.05)	-0.3 (± 0.05)	-0.3 (± 0.05)	-0.3 (± 0.07)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 102, 104, NA, NA, 103)	9999 (± 9999)	-0.09 (± 0.05)		
Month 3 (n=101, 102, 101, NA, NA, 102)	9999 (± 9999)	-0.12 (± 0.051)		
Month 6 (n=100, 99, 99, 48, 48, NA)	-0.3 (± 0.06)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	-0.3 (± 0.07)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	-0.2 (± 0.07)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Usual Activities at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Usual Activities at Months 1, 3, 6, 9, and 12

End point description:

The EQ-5D is a descriptive system of health-related quality of life states consisting of 5 dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) each of which can take 1 of 3 responses. The responses record 3 levels of severity (no problems/some or moderate problems/extreme problems) within a particular EQ-5D dimension. Standard vertical 0 to 100 mm visual analogue scale (similar to a thermometer) for recording an individual's rating for their current health-related quality of life state. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	103	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 102, 104, NA, NA, 103)	-0.17 (± 0.043)	-0.19 (± 0.043)	-0.21 (± 0.044)	9999 (± 9999)
Month 3 (n=101, 102, 101, NA, NA, 102)	-0.24 (± 0.049)	-0.29 (± 0.049)	-0.29 (± 0.049)	9999 (± 9999)
Month 6 (n=100, 99, 99, 48, 47, NA)	-0.3 (± 0.05)	-0.3 (± 0.05)	-0.4 (± 0.05)	-0.3 (± 0.07)
Month 9 (n=99, 97, 96, 47, 46, NA)	-0.3 (± 0.05)	-0.4 (± 0.05)	-0.4 (± 0.05)	-0.3 (± 0.07)
Month 12 (n=96, 96, 94, 44, 44, NA)	-0.3 (± 0.05)	-0.4 (± 0.05)	-0.4 (± 0.05)	-0.3 (± 0.07)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 102, 104, NA, NA, 103)	9999 (± 9999)	-0.06 (± 0.047)		
Month 3 (n=101, 102, 101, NA, NA, 102)	9999 (± 9999)	-0.17 (± 0.052)		
Month 6 (n=100, 99, 99, 48, 47, NA)	-0.3 (± 0.07)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	-0.4 (± 0.07)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	-0.3 (± 0.07)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Pain/Discomfort at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Pain/Discomfort at Months 1, 3, 6, 9, and 12

End point description:

The EQ-5D is a descriptive system of health-related quality of life states consisting of 5 dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) each of which can take 1 of 3 responses. The responses record 3 levels of severity (no problems/some or moderate problems/extreme problems) within a particular EQ-5D dimension. Standard vertical 0 to 100 mm visual analogue scale (similar to a thermometer) for recording an individual's rating for their current health-related quality of life state. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103, 104, NA, NA, 103)	-0.14 (± 0.039)	-0.25 (± 0.04)	-0.19 (± 0.04)	9999 (± 9999)
Month 3 (n=101, 103, 101, NA, NA, 102)	-0.25 (± 0.044)	-0.27 (± 0.044)	-0.28 (± 0.045)	9999 (± 9999)
Month 6 (n=100, 100, 99, 48, 48, NA)	-0.3 (± 0.05)	-0.4 (± 0.05)	-0.3 (± 0.05)	-0.3 (± 0.07)
Month 9 (n=99, 97, 96, 47, 46, NA)	-0.3 (± 0.05)	-0.3 (± 0.05)	-0.3 (± 0.05)	-0.4 (± 0.07)
Month 12 (n=96, 96, 94, 44, 44, NA)	-0.3 (± 0.05)	-0.4 (± 0.05)	-0.3 (± 0.05)	-0.2 (± 0.07)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103, 104, NA, NA, 103)	9999 (± 9999)	-0.08 (± 0.043)		
Month 3 (n=101, 103, 101, NA, NA, 102)	9999 (± 9999)	-0.08 (± 0.047)		
Month 6 (n=100, 100, 99, 48, 48, NA)	-0.4 (± 0.07)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	-0.4 (± 0.07)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	-0.3 (± 0.07)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Anxiety/Depression at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Anxiety/Depression at Months 1, 3, 6, 9, and 12

End point description:

The EQ-5D is a descriptive system of health-related quality of life states consisting of 5 dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) each of which can take 1 of 3 responses. The responses record 3 levels of severity (no problems/some or moderate problems/extreme problems) within a particular EQ-5D dimension. Standard vertical 0 to 100 mm visual analogue scale (similar to a thermometer) for recording an individual's rating for their current health-related quality of life state. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103, 104, NA, NA, 103)	-0.25 (± 0.051)	-0.22 (± 0.052)	-0.27 (± 0.053)	9999 (± 9999)
Month 3 (n=101, 103, 100, NA, NA, 102)	-0.25 (± 0.055)	-0.17 (± 0.055)	-0.32 (± 0.056)	9999 (± 9999)
Month 6 (n=100, 100, 99, 48, 48, NA)	-0.3 (± 0.05)	-0.3 (± 0.05)	-0.3 (± 0.05)	-0.3 (± 0.08)
Month 9 (n=99, 97, 96, 47, 46, NA)	-0.3 (± 0.05)	-0.4 (± 0.05)	-0.4 (± 0.06)	-0.2 (± 0.08)
Month 12 (n=96, 96, 94, 44, 44, NA)	-0.3 (± 0.05)	-0.4 (± 0.05)	-0.4 (± 0.06)	-0.2 (± 0.08)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				

Month 1 (n=105, 103, 104, NA, NA, 103)	9999 (± 9999)	-0.21 (± 0.056)		
Month 3 (n=101, 103, 100, NA, NA, 102)	9999 (± 9999)	-0.21 (± 0.059)		
Month 6 (n=100, 100, 99, 48, 48, NA)	-0.2 (± 0.08)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	-0.3 (± 0.08)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	-0.3 (± 0.08)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Patient's Health State Today at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Patient's Health State Today at Months 1, 3, 6, 9, and 12

End point description:

The EQ-5D is a descriptive system of health-related quality of life states consisting of 5 dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) each of which can take 1 of 3 responses. The responses record 3 levels of severity (no problems/some or moderate problems/extreme problems) within a particular EQ-5D dimension. Standard vertical 0 to 100 mm visual analogue scale (similar to a thermometer) for recording an individual's rating for their current health-related quality of life state. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: mm				
least squares mean (standard error)				
Month 1 (n=105, 103, 104, NA, NA, 103)	10.75 (± 1.859)	10.81 (± 1.88)	10.27 (± 1.917)	9999 (± 9999)
Month 3 (n=101, 103, 101, NA, NA, 101)	14 (± 2.1)	15.83 (± 2.092)	13.1 (± 2.138)	9999 (± 9999)
Month 6 (n=100, 100, 99, 48, 48, NA)	19.5 (± 2.08)	15.7 (± 2.09)	15.5 (± 2.12)	14.7 (± 2.97)
Month 9 (n=99, 97, 96, 47, 46, NA)	19.2 (± 2.21)	15.9 (± 2.23)	18.2 (± 2.26)	12.8 (± 3.16)
Month 12 (n=96, 96, 94, 44, 44, NA)	20.7 (± 2.09)	19.8 (± 2.09)	16.5 (± 2.14)	16 (± 3.02)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		

Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: mm				
least squares mean (standard error)				
Month 1 (n=105, 103, 104, NA, NA, 103)	9999 (± 9999)	6.59 (± 2.027)		
Month 3 (n=101, 103, 101, NA, NA, 101)	9999 (± 9999)	6.37 (± 2.242)		
Month 6 (n=100, 100, 99, 48, 48, NA)	16.6 (± 3)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	21.5 (± 3.21)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	19.8 (± 3.05)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F) Scores: Total Score at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F) Scores: Total Score at Months 1, 3, 6, 9, and 12

End point description:

FACIT-F is a 13-item questionnaire, with each item score ranging from 0 to 4. Three endpoints are derived: change in FACIT-F total score, change in FACIT-F experience domain score, and change in FACIT-F impact domain score. FACIT-F total score (range 0-52) is calculated by summing the 13 items. FACIT-F experience domain score (range 0-20) is calculated by summing 5 items : I feel fatigued, I feel weak all over, I feel listless (“washed out”), I feel tired, and I have energy, while FACIT-F impact domain score (range 0-32) is calculated by summing the remaining 8 items. All responses are added with equal weight to obtain the total score. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103, 104, NA, NA, 103)	5.2 (± 0.77)	4.4 (± 0.78)	4.2 (± 0.79)	9999 (± 9999)
Month 3 (n=102, 102, 101, NA, NA, 102)	7 (± 0.85)	6 (± 0.85)	6 (± 0.87)	9999 (± 9999)
Month 6 (n=100, 100, 99,48, 48, NA)	7.9 (± 0.89)	8 (± 0.89)	6.5 (± 0.91)	6.5 (± 1.26)
Month 9 (n=99, 97, 96, 47, 46, NA)	7.9 (± 0.92)	7.4 (± 0.92)	6.5 (± 0.94)	5.5 (± 1.31)
Month 12 (n=96, 96, 94, 44, 44, NA)	8.5 (± 0.95)	8.4 (± 0.95)	6.9 (± 0.97)	5.7 (± 1.36)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103, 104, NA, NA, 103)	9999 (± 9999)	2.7 (± 0.84)		
Month 3 (n=102, 102, 101, NA, NA, 102)	9999 (± 9999)	3.3 (± 0.91)		
Month 6 (n=100, 100, 99,48, 48, NA)	7.2 (± 1.28)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	8.4 (± 1.33)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	7.6 (± 1.38)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F) Scores: Experience Domain Score at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F) Scores: Experience Domain Score at Months 1, 3, 6, 9, and 12

End point description:

FACIT-F is a 13-item questionnaire, with each item score ranging from 0 to 4. Three endpoints are derived: change in FACIT-F total score, change in FACIT-F experience domain score, and change in FACIT-F impact domain score. FACIT-F total score (range 0-52) is calculated by summing the 13 items. FACIT-F experience domain score (range 0-20) is calculated by summing 5 items : I feel fatigued, I feel weak all over, I feel listless (“washed out”), I feel tired, and I have energy, while FACIT-F impact domain score (range 0-32) is calculated by summing the remaining 8 items. All responses are added with equal weight to obtain the total score. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103, 104, NA, NA, 103)	2.4 (± 0.35)	2.1 (± 0.35)	2.1 (± 0.36)	9999 (± 9999)

Month 3 (n=102, 102, 101, NA, NA, 102)	3.3 (± 0.38)	2.8 (± 0.38)	2.9 (± 0.39)	9999 (± 9999)
Month 6 (n=100, 100, 99,48, 48, NA)	3.6 (± 0.4)	3.3 (± 0.4)	3.2 (± 0.41)	3 (± 0.57)
Month 9 (n=99, 97, 96, 47, 46, NA)	3.6 (± 0.42)	3.3 (± 0.42)	3.3 (± 0.43)	2.7 (± 0.59)
Month 12 (n=96, 96, 94, 44, 44, NA)	3.9 (± 0.44)	3.7 (± 0.44)	3.2 (± 0.45)	2.7 (± 0.63)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103, 104, NA, NA, 103)	9999 (± 9999)	1.2 (± 0.38)		
Month 3 (n=102, 102, 101, NA, NA, 102)	9999 (± 9999)	1.6 (± 0.41)		
Month 6 (n=100, 100, 99,48, 48, NA)	3.3 (± 0.58)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	3.9 (± 0.6)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	3.4 (± 0.63)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F) Scores: Impact Domain Score at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F) Scores: Impact Domain Score at Months 1, 3, 6, 9, and 12

End point description:

FACIT-F is a 13-item questionnaire, with each item score ranging from 0 to 4. Three endpoints are derived: change in FACIT-F total score, change in FACIT-F experience domain score, and change in FACIT-F impact domain score. FACIT-F total score (range 0-52) is calculated by summing the 13 items. FACIT-F experience domain score (range 0-20) is calculated by summing 5 items : I feel fatigued, I feel weak all over, I feel listless (“washed out”), I feel tired, and I have energy, while FACIT-F impact domain score (range 0-32) is calculated by summing the remaining 8 items. All responses are added with equal weight to obtain the total score. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	104	106	52
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103, 104, NA, NA, 103)	2.9 (± 0.47)	2.3 (± 0.48)	2.1 (± 0.49)	9999 (± 9999)
Month 3 (n=102, 102, 101, NA, NA, 102)	3.8 (± 0.52)	3.2 (± 0.52)	3.2 (± 0.53)	9999 (± 9999)
Month 6 (n=100, 100, 99,48, 48, NA)	4.3 (± 0.53)	4.7 (± 0.53)	3.4 (± 0.54)	3.5 (± 0.75)
Month 9 (n=99, 97, 96, 47, 46, NA)	4.3 (± 0.55)	4.1 (± 0.55)	3.3 (± 0.56)	2.8 (± 0.78)
Month 12 (n=96, 96, 94, 44, 44, NA)	4.6 (± 0.57)	4.7 (± 0.57)	3.7 (± 0.58)	2.9 (± 0.82)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	104		
Units: Units on a scale				
least squares mean (standard error)				
Month 1 (n=105, 103, 104, NA, NA, 103)	9999 (± 9999)	1.5 (± 0.52)		
Month 3 (n=102, 102, 101, NA, NA, 102)	9999 (± 9999)	1.8 (± 0.56)		
Month 6 (n=100, 100, 99,48, 48, NA)	4 (± 0.76)	9999 (± 9999)		
Month 9 (n=99, 97, 96, 47, 46, NA)	4.6 (± 0.8)	9999 (± 9999)		
Month 12 (n=96, 96, 94, 44, 44, NA)	4.3 (± 0.82)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Scores Evaluating Spondylitis Using the Bath Anklyosing Spondylitis Disease Activity Index (BASDAI) at Months 1, 3, 6, 9, and 12

End point title	Change From Baseline in Scores Evaluating Spondylitis Using the Bath Anklyosing Spondylitis Disease Activity Index (BASDAI) at Months 1, 3, 6, 9, and 12

End point description:

BASDAI is a validated self-assessment tool used to determine disease activity in participants with ankylosing spondylitis. Utilizing a visual analog scale of 0-10 (0=none and 10=very severe) participants answer 6 questions measuring discomfort, pain, and fatigue. The final BASDAI score averages the individual assessments for a final score ranging 0-10. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type	Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

End point values	Tofacitinib, 5 mg, twice daily	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Placebo/Tofacitinib, 5 mg, twice daily
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	21	10	10
Units: cm				
least squares mean (standard error)				
Month 1 (n=24, 21, 10, NA, NA, 22)	-1.23 (± 0.537)	-1.6 (± 0.508)	-2.3 (± 0.673)	9999 (± 9999)
Month 3 (n=24, 21, 10, NA, NA, 22)	-1.83 (± 0.579)	-2.78 (± 0.559)	-2.93 (± 0.753)	9999 (± 9999)
Month 6 (n=23, 21, 10, 9, 11, NA)	-2.24 (± 0.58)	-2.35 (± 0.56)	-3.58 (± 0.758)	-2.85 (± 0.778)
Month 9 (n=23, 20, 10, 9, 9, NA)	-2.06 (± 0.575)	-2.71 (± 0.558)	2.66 (± 0.747)	-3 (± 0.77)
Month 12 (n=23, 19, 10, 9, 9, NA)	-2.5 (± 0.594)	-3.3 (± 0.587)	-2.42 (± 0.779)	-2.31 (± 0.808)

End point values	Placebo/Tofacitinib, 10 mg, twice daily	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	12	22		
Units: cm				
least squares mean (standard error)				
Month 1 (n=24, 21, 10, NA, NA, 22)	9999 (± 9999)	-1.27 (± 0.581)		
Month 3 (n=24, 21, 10, NA, NA, 22)	9999 (± 9999)	-1.6 (± 0.624)		
Month 6 (n=23, 21, 10, 9, 11, NA)	-3.31 (± 0.744)	9999 (± 9999)		
Month 9 (n=23, 20, 10, 9, 9, NA)	-3.35 (± 0.761)	9999 (± 9999)		
Month 12 (n=23, 19, 10, 9, 9, NA)	-2.67 (± 0.806)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events (AEs) were assessed from first administration of study treatment through last visit. Serious AEs (SAEs) were assessed from informed consent through and including 28 calendar days after last administration of investigational product.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

Reporting groups

Reporting group title	Tofacitinib, 10 mg, twice daily

Reporting group description:

Participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks.

Reporting group title	Adalimumab, 40 mg, every 2 weeks

Reporting group description:

Participants received 2 placebo tablets twice daily and adalimumab, 40 mg, administered subcutaneously every 2 weeks.

Reporting group title	Tofacitinib, 5 mg, twice daily

Reporting group description:

Participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo administered every 2 weeks.

Reporting group title	Placebo/Tofacitinib, 10 mg, twice daily

Reporting group description:

Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks

Reporting group title	Placebo/Tofacitinib, 5 mg, twice daily

Reporting group description:

Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo every 2 weeks.

Serious adverse events	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Tofacitinib, 5 mg, twice daily
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 104 (3.85%)	9 / 106 (8.49%)	8 / 107 (7.48%)
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)			
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected neoplasm			

subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the vulva			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	0 / 107 (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
Hypertension			
subjects affected / exposed	1 / 104 (0.96%)	0 / 106 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Cystocele			
subjects affected / exposed	1 / 104 (0.96%)	0 / 106 (0.00%)	0 / 107 (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
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 104 (0.00%)	1 / 106 (0.94%)	0 / 107 (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
Rectocele			
subjects affected / exposed	1 / 104 (0.96%)	0 / 106 (0.00%)	0 / 107 (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

Uterine polyp			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	0 / 107 (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			
Bronchial hyperreactivity			
subjects affected / exposed	1 / 104 (0.96%)	0 / 106 (0.00%)	0 / 107 (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
Bronchospasm			
subjects affected / exposed	1 / 104 (0.96%)	0 / 106 (0.00%)	0 / 107 (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
Dyspnoea exertional			
subjects affected / exposed	0 / 104 (0.00%)	1 / 106 (0.94%)	0 / 107 (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
Hypoxia			
subjects affected / exposed	1 / 104 (0.96%)	0 / 106 (0.00%)	0 / 107 (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
Injury, poisoning and procedural complications			
Joint injury			
subjects affected / exposed	0 / 104 (0.00%)	1 / 106 (0.94%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 104 (0.00%)	1 / 106 (0.94%)	0 / 107 (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
Bradycardia			

subjects affected / exposed	0 / 104 (0.00%)	1 / 106 (0.94%)	0 / 107 (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
Cardiac arrest			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	0 / 107 (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
Nervous system disorders			
Migraine			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 104 (0.00%)	1 / 106 (0.94%)	0 / 107 (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
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	0 / 107 (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
Chronic gastritis			
subjects affected / exposed	0 / 104 (0.00%)	1 / 106 (0.94%)	0 / 107 (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
Diverticulum			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	0 / 107 (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
Nausea			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			

Bile duct stone			
subjects affected / exposed	0 / 104 (0.00%)	1 / 106 (0.94%)	0 / 107 (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
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermal cyst			
subjects affected / exposed	1 / 104 (0.96%)	0 / 106 (0.00%)	0 / 107 (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
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	0 / 107 (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 disorder			
subjects affected / exposed	0 / 104 (0.00%)	1 / 106 (0.94%)	0 / 107 (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
Musculoskeletal chest pain			
subjects affected / exposed	0 / 104 (0.00%)	1 / 106 (0.94%)	0 / 107 (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
Psoriatic arthropathy			

subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	0 / 107 (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			
Appendicitis			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	0 / 107 (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
Herpes simplex			
subjects affected / exposed	0 / 104 (0.00%)	1 / 106 (0.94%)	0 / 107 (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
Influenza			
subjects affected / exposed	1 / 104 (0.96%)	0 / 106 (0.00%)	0 / 107 (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
Pneumonia			
subjects affected / exposed	0 / 104 (0.00%)	0 / 106 (0.00%)	0 / 107 (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
Pyoderma streptococcal			
subjects affected / exposed	0 / 104 (0.00%)	1 / 106 (0.94%)	0 / 107 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 104 (0.96%)	0 / 106 (0.00%)	0 / 107 (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

Serious adverse events	Placebo/Tofacitinib, 10 mg, twice daily	Placebo/Tofacitinib, 5 mg, twice daily	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 53 (7.55%)	3 / 52 (5.77%)	
number of deaths (all causes)	0	1	
number of deaths resulting from adverse events	0	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected neoplasm			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the vulva			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Cystocele			

subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectocele			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	1 / 53 (1.89%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			

Joint injury			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 53 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Nervous system disorders			
Migraine			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastritis			

subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	1 / 53 (1.89%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermal cyst			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy			
subjects affected / exposed	1 / 53 (1.89%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Musculoskeletal and connective tissue disorders			
Intervertebral disc disorder			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriatic arthropathy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes simplex			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pyoderma streptococcal			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 53 (0.00%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Tofacitinib, 10 mg, twice daily	Adalimumab, 40 mg, every 2 weeks	Tofacitinib, 5 mg, twice daily
Total subjects affected by non-serious adverse events			
subjects affected / exposed	43 / 104 (41.35%)	43 / 106 (40.57%)	31 / 107 (28.97%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	3 / 104 (2.88%)	8 / 106 (7.55%)	3 / 107 (2.80%)
occurrences (all)	3	11	3
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 104 (0.96%)	7 / 106 (6.60%)	0 / 107 (0.00%)
occurrences (all)	1	8	0
Blood creatine phosphokinase increased			
subjects affected / exposed	5 / 104 (4.81%)	3 / 106 (2.83%)	5 / 107 (4.67%)
occurrences (all)	5	3	7
Nervous system disorders			
Headache			
subjects affected / exposed	11 / 104 (10.58%)	7 / 106 (6.60%)	5 / 107 (4.67%)
occurrences (all)	17	10	6
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 104 (0.96%)	2 / 106 (1.89%)	1 / 107 (0.93%)
occurrences (all)	1	2	1
Nausea			

subjects affected / exposed	4 / 104 (3.85%)	6 / 106 (5.66%)	3 / 107 (2.80%)
occurrences (all)	4	6	3
Musculoskeletal and connective tissue disorders			
Spinal pain			
subjects affected / exposed	1 / 104 (0.96%)	3 / 106 (2.83%)	2 / 107 (1.87%)
occurrences (all)	1	3	2
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	12 / 104 (11.54%)	11 / 106 (10.38%)	8 / 107 (7.48%)
occurrences (all)	13	14	9
Pharyngitis			
subjects affected / exposed	6 / 104 (5.77%)	7 / 106 (6.60%)	5 / 107 (4.67%)
occurrences (all)	6	9	5
Upper respiratory tract infection			
subjects affected / exposed	11 / 104 (10.58%)	8 / 106 (7.55%)	10 / 107 (9.35%)
occurrences (all)	11	9	13
Urinary tract infection			
subjects affected / exposed	4 / 104 (3.85%)	4 / 106 (3.77%)	2 / 107 (1.87%)
occurrences (all)	5	4	4

Non-serious adverse events	Placebo/Tofacitinib, 10 mg, twice daily	Placebo/Tofacitinib, 5 mg, twice daily	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 53 (41.51%)	15 / 52 (28.85%)	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 53 (1.89%)	3 / 52 (5.77%)	
occurrences (all)	1	3	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 53 (1.89%)	1 / 52 (1.92%)	
occurrences (all)	1	1	
Blood creatine phosphokinase increased			
subjects affected / exposed	5 / 53 (9.43%)	1 / 52 (1.92%)	
occurrences (all)	6	1	
Nervous system disorders			

Headache			
subjects affected / exposed	4 / 53 (7.55%)	2 / 52 (3.85%)	
occurrences (all)	7	3	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 53 (5.66%)	0 / 52 (0.00%)	
occurrences (all)	4	0	
Nausea			
subjects affected / exposed	1 / 53 (1.89%)	0 / 52 (0.00%)	
occurrences (all)	3	0	
Musculoskeletal and connective tissue disorders			
Spinal pain			
subjects affected / exposed	0 / 53 (0.00%)	3 / 52 (5.77%)	
occurrences (all)	0	4	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	4 / 53 (7.55%)	4 / 52 (7.69%)	
occurrences (all)	4	5	
Pharyngitis			
subjects affected / exposed	3 / 53 (5.66%)	0 / 52 (0.00%)	
occurrences (all)	3	0	
Upper respiratory tract infection			
subjects affected / exposed	5 / 53 (9.43%)	5 / 52 (9.62%)	
occurrences (all)	6	5	
Urinary tract infection			
subjects affected / exposed	4 / 53 (7.55%)	1 / 52 (1.92%)	
occurrences (all)	4	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 May 2013	This amendment included country-specific requirement for participants in Taiwan to be >20 years old for inclusion, updated footnotes of schedule of activities to show that collection of banked biospecimens were not mandatory per regulatory feedback, exclusion criterion 6d revised absolute lymphocyte count from <0.5 × 109/L (<500 mm3) to <1.0 × 109/L (<1000 mm3) as exclusion criterion per regulatory feedback (EU Competent Authorities that participated in the Voluntary Harmonization Procedure for Clinical Trial Applications).
13 December 2013	Inclusion criterion 1: clarified PsA criteria for enrollment to state that a participant had signs and symptoms consistent with the diagnosis of PsA for at least 6 months. Inclusion criterion 6: standardised washout of biologics to 6 months per regulatory agency request (Canada Health Ministry). Addition of 'localised' infection to exclusion criterion 15 per regulatory agency request (German BfArM). Addition of new exclusion criterion (26) for participants at risk of gastrointestinal perforation per latest Investigator's Brochure. Clarification of use of sexual abstinence as contraceptive method only when consistent with preferred and usual participant lifestyle, per regulatory agency request (UK Ethics Committee). Added contraception advice for adalimumab: participants were advised to use effective contraception for 5 months following administration of the injectable medication or as per local adalimumab label/summary of product characteristics.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported