Clinical trial results:
Multicenter, open label study to evaluate the predictability of early response to certolizumab pegol (in combination with methotrexate) as confirmed at week 52 in subjects with moderate-severe rheumatoid arthritis (RA)

Summary

EudraCT number	2011-000385-35
Trial protocol	IT
Global end of trial date	12 May 2015

Results information

Result version number	v1 (current)
This version publication date	05 February 2016
First version publication date	05 February 2016

Trial information

Trial identification

Sponsor protocol code	RA0069

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01443364
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UCB Pharma S.p.a.
Sponsor organisation address	Via Gadames 57, Milano, Italy, 20151
Public contact	Clinical Trial Registries and Results Disclosure, UCB BIOSCIENCES GmbH, +49 2173 48 15 15, clinicaltrials@ucb.com
Scientific contact	Clinical Trial Registries and Results Disclosure, UCB BIOSCIENCES GmbH, +49 2173 48 15 15, clinicaltrials@ucb.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	09 July 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 May 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To detect the time-point of clinical response with the highest predictive value of long term efficacy (at Week 52).

Protection of trial subjects:

Not applicable

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	05 December 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Italy: 132
Worldwide total number of subjects	132
EEA total number of subjects	132

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)	94
From 65 to 84 years	38
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study started to enroll patients in December 2011 and concluded in May 2015.

Pre-assignment

Screening details:

Participant Flow refers to all subjects randomized who have received at least one dose of study medication.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Certolizumab pegol

Arm description:

Subjects will be treated for 52 weeks with Certolizumab Pegol (CZP) (administration every two weeks) in combination with Methotrexate (MTX) (administration weekly). Dosing regimen of CZP consists of 3 administrations of 400 mg at Weeks 0, 2 and 4 followed by 200 mg every other week up to and including Week 50.

Arm type	Experimental
Investigational medicinal product name	Certolizumab pegol
Investigational medicinal product code	Cimzia
Other name	
Pharmaceutical forms	Solution for infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Pre-filled syringe with 1 ml of liquid at CZP dosage of 200 mg/ml

Number of subjects in period 1	Certolizumab pegol
Started	132
Completed	91
Not completed	41
Consent withdrawn by subject	5
Other Reason	4
AE, non-serious non-fatal	8
SAE, non-fatal+AE, non-serious non-fatal	1
Lost to follow-up	3
SAE, non-fatal	6
Lack of efficacy	14

Baseline characteristics

Reporting groups	
Reporting group title	Certolizumab pegol
Reporting group description:	
Subjects will be treated for 52 weeks with Certolizumab Pegol (CZP) (administration every two weeks) in combination with Methotrexate (MTX) (administration weekly). Dosing regimen of CZP consists of 3 administrations of 400 mg at Weeks 0, 2 and 4 followed by 200 mg every other week up to and including Week 50.	

Reporting group values	Certolizumab pegol	Total	
Number of subjects	132	132	
Age Categorical Units: Subjects			
<=18 years	0	0	
Between 18 and 65 years	94	94	
>=65 years	38	38	
Age Continuous Units: years			
arithmetic mean	54.8		
standard deviation	± 13.2	-	
Gender Categorical Units: Subjects			
Female	108	108	
Male	24	24	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	35	35	
Not Hispanic or Latino	97	97	
Weight Units: kilogram			
arithmetic mean	69.33		
standard deviation	± 14.1	-	
BMI Units: kg/m^2			
arithmetic mean	25.66		
standard deviation	± 4.52	-	
Height Units: centimeter			
arithmetic mean	164.16		
standard deviation	± 8.48	-	

End points

End points reporting groups

Reporting group title	Certolizumab pegol

Reporting group description:

Subjects will be treated for 52 weeks with Certolizumab Pegol (CZP) (administration every two weeks) in combination with Methotrexate (MTX) (administration weekly). Dosing regimen of CZP consists of 3 administrations of 400 mg at Weeks 0, 2 and 4 followed by 200 mg every other week up to and including Week 50.

Subject analysis set title	Certolizumab pegol (FAS)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects will be treated for 52 weeks with Certolizumab Pegol (CZP) (administration every two weeks) in combination with Methotrexate (MTX) (administration weekly). Dosing regimen of CZP consists of 3 administrations of 400 mg at Weeks 0, 2 and 4 followed by 200 mg every other week up to and including Week 50.

Primary: The percentage of subjects with clinical response at Week 12 who also had clinical response at Week 52

End point title	The percentage of subjects with clinical response at Week 12 who also had clinical response at Week 52[1]

End point description:

Clinical response is defined as a reduction from Baseline (Week 0) of more than 1.2 scores in the Disease Activity Score28 [Erythrocyte Sedimentation Rate] (DAS28-ESR) scoring system

End point type	Primary

End point timeframe:

From Baseline to Week 12 and Week 52

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	131			
Units: percentage of subjects				
number (confidence interval 95%)				
percentage of subjects	69.1 (58.78 to 78.27)			

Statistical analyses

No statistical analyses for this end point

Primary: The percentage of subjects with clinical response at Week 8 who also had clinical response at Week 52

End point title	The percentage of subjects with clinical response at Week 8 who also had clinical response at Week 52[2]

End point description:

Clinical response is defined as a reduction from Baseline (Week 0) of more than 1.2 scores in the Disease Activity Score28 [Erythrocyte Sedimentation Rate] (DAS28-ESR) scoring system

End point type	Primary

End point timeframe:

From Baseline to Week 8 and Week 52

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	131			
Units: percentage of subjects				
number (confidence interval 95%)				
percentage of subjects	69.8 (59.57 to 78.75)			

Statistical analyses

No statistical analyses for this end point

Primary: The percentage of subjects with clinical response at Week 6 who also had clinical response at Week 52

End point title	The percentage of subjects with clinical response at Week 6 who also had clinical response at Week 52[3]

End point description:

Clinical response is defined as a reduction from Baseline (Week 0) of more than 1.2 scores in the Disease Activity Score28 [Erythrocyte Sedimentation Rate] (DAS28-ESR) scoring system

End point type	Primary

End point timeframe:

From Baseline to Week 6 and Week 52

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	131			
Units: percentage of subjects				
number (confidence interval 95%)				
percentage of subjects	65.2 (54.33 to 74.96)			

Statistical analyses

No statistical analyses for this end point

Primary: The percentage of subjects with clinical response at Week 4 who also had clinical response at Week 52

End point title	The percentage of subjects with clinical response at Week 4 who also had clinical response at Week 52[4]

End point description:

Clinical response is defined as a reduction from Baseline (Week 0) of more than 1.2 scores in the Disease Activity Score28 [Erythrocyte Sedimentation Rate] (DAS28-ESR) scoring system

End point type	Primary

End point timeframe:

From Baseline to Week 4 and Week 52

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	131			
Units: percentage of subjects				
number (confidence interval 95%)				
percentage of subjects	66.7 (56.13 to 76.11)			

Statistical analyses

No statistical analyses for this end point

Primary: The percentage of subjects with clinical response at Week 2 who also had clinical response at Week 52

End point title	The percentage of subjects with clinical response at Week 2 who also had clinical response at Week 52[5]

End point description:

Clinical response is defined as a reduction from Baseline (Week 0) of more than 1.2 scores in the Disease Activity Score28 [Erythrocyte Sedimentation Rate] (DAS28-ESR) scoring system

End point type	Primary

End point timeframe:

From Baseline to Week 2 and Week 52

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	131			
Units: percentage of subjects				
number (confidence interval 95%)				
percentage of subjects	64.9 (52.89 to 75.61)			

Statistical analyses

No statistical analyses for this end point

Primary: The percentage of subjects with clinical response at Week 1 who also had clinical response at Week 52

End point title	The percentage of subjects with clinical response at Week 1 who also had clinical response at Week 52[6]

End point description:

Clinical response is defined as a reduction from Baseline (Week 0) of more than 1.2 scores in the Disease Activity Score28 [Erythrocyte Sedimentation Rate] (DAS28-ESR) scoring system

End point type	Primary

End point timeframe:

From Baseline to Week 1 and Week 52

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	131			
Units: percentage of subjects				
number (confidence interval 95%)				
percentage of subjects	55.8 (39.88 to 70.92)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the synovial fluid and proliferation at Week 52

End point title	Change from Baseline in the synovial fluid and proliferation at Week 52

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 52

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-9 to 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the synovial fluid and proliferation at Week 36

End point title	Change from Baseline in the synovial fluid and proliferation at Week 36

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 36

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-9 to 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the synovial fluid and proliferation at Week 24

End point title	Change from Baseline in the synovial fluid and proliferation at Week 24

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 24

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-9 to 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the synovial fluid and proliferation at Week 12

End point title	Change from Baseline in the synovial fluid and proliferation at Week 12

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 12

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-12 to 5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the synovial fluid and proliferation at Week 8

End point title	Change from Baseline in the synovial fluid and proliferation at Week 8

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 8

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-12 to 2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the synovial fluid and proliferation at Week 6

End point title	Change from Baseline in the synovial fluid and proliferation at Week 6

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 6

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-10 to 2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the synovial fluid and proliferation at Week 4

End point title	Change from Baseline in the synovial fluid and proliferation at Week 4

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 4

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-8 to 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the synovial fluid and proliferation at Week 2

End point title	Change from Baseline in the synovial fluid and proliferation at Week 2

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 2

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	57			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-5 to 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the synovial fluid and proliferation at Week 1

End point title	Change from Baseline in the synovial fluid and proliferation at Week 1

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score

indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 1

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	53			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-5 to 3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Doppler signal and blood flow at Week 52

End point title	Change from Baseline in the Doppler signal and blood flow at Week 52

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 52

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-12 to 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Doppler signal and blood flow at Week 36

End point title	Change from Baseline in the Doppler signal and blood flow at Week 36

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 36

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-11 to 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Doppler signal and blood flow at Week 24

End point title	Change from Baseline in the Doppler signal and blood flow at Week 24

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 24

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-11 to 6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Doppler signal and blood flow at Week 12

End point title	Change from Baseline in the Doppler signal and blood flow at

	Week 12

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 12

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-12 to 9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Doppler signal and blood flow at Week 8

End point title	Change from Baseline in the Doppler signal and blood flow at Week 8

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 8

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-12 to 2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Doppler signal and blood flow at Week 6	
End point title	Change from Baseline in the Doppler signal and blood flow at Week 6

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 6

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-12 to 2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Doppler signal and blood flow at Week 4	
End point title	Change from Baseline in the Doppler signal and blood flow at Week 4

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 4

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-0.5 (-10 to 2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Doppler signal and blood flow at Week 2

End point title	Change from Baseline in the Doppler signal and blood flow at Week 2

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 2

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	57			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-10 to 3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Doppler signal and blood flow at Week 1

End point title	Change from Baseline in the Doppler signal and blood flow at Week 1

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 1

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	53			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-10 to 3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Cartilage damage at Week 52

End point title	Change from Baseline in the Cartilage damage at Week 52

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 52

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	55			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-11 to 8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Cartilage damage at Week 36

End point title	Change from Baseline in the Cartilage damage at Week 36

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 36

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	55			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-12 to 16)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Cartilage damage at Week 24

End point title	Change from Baseline in the Cartilage damage at Week 24

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 24

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	54			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-13 to 11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Cartilage damage at Week 12

End point title	Change from Baseline in the Cartilage damage at Week 12

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 12

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	54			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-11 to 11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Cartilage damage at Week 8

End point title	Change from Baseline in the Cartilage damage at Week 8

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 8

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	54			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-11 to 9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Cartilage damage at Week 6

End point title	Change from Baseline in the Cartilage damage at Week 6

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 6

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	54			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-11 to 7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Cartilage damage at Week 4

End point title	Change from Baseline in the Cartilage damage at Week 4

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 4

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	54			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-11 to 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Cartilage damage at Week 2

End point title	Change from Baseline in the Cartilage damage at Week 2

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 2

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	53			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-11 to 9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Cartilage damage at Week 1

End point title	Change from Baseline in the Cartilage damage at Week 1

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 1

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	50			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-8 to 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the bone erosion at Week 52

End point title	Change from Baseline in the bone erosion at Week 52

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 52

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-5 to 3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the bone erosion at Week 36

End point title	Change from Baseline in the bone erosion at Week 36

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 36

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-5 to 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the bone erosion at Week 24

End point title	Change from Baseline in the bone erosion at Week 24

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 24

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-5 to 10)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the bone erosion at Week 12

End point title	Change from Baseline in the bone erosion at Week 12

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 12

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-5 to 3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the bone erosion at Week 8

End point title	Change from Baseline in the bone erosion at Week 8

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 8

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-5 to 5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the bone erosion at Week 6

End point title	Change from Baseline in the bone erosion at Week 6

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 6

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-5 to 3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the bone erosion at Week 4

End point title	Change from Baseline in the bone erosion at Week 4

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 4

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-5 to 3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the bone erosion at Week 2

End point title	Change from Baseline in the bone erosion at Week 2

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 2

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	57			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-4 to 2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the bone erosion at Week 1

End point title	Change from Baseline in the bone erosion at Week 1

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 1

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	53			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (-4 to 2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 52

End point title	Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 52

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 52

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-3 (-20 to 5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 36

End point title	Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 36

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 36

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-3 (-20 to 6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 24

End point title	Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 24

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 24

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-3 (-20 to 10)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 12

End point title	Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 12

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 12

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-3 (-23 to 14)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 8

End point title	Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 8

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 8

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-3 (-23 to 3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 6

End point title	Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 6

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 6

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-2.5 (-20 to 3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 4

End point title	Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 4

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 4

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-2.5 (-17 to 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 2

End point title	Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 2

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 2

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	57			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-2 (-13 to 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 1

End point title	Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 1

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

From Baseline to Week 1

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	53			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-13 to 3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 52

End point title	Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 52

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 52

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	55			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-2 (-15 to 9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 36

End point title	Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 36

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 36

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	55			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-2 (-15 to 17)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 24

End point title	Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 24

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 24

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	54			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1.5 (-15 to 10)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 12

End point title	Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 12

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 12

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	54			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-2 (-15 to 11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 8

End point title	Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 8

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 8

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	54			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-2 (-13 to 11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 6

End point title	Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 6

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 6

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	54			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-2 (-15 to 5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 4

End point title	Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 4

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 4

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	54			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-15 to 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 2

End point title	Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 2

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 2

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	53			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-15 to 9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 1

End point title	Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 1

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

From Baseline to Week 1

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	50			
Units: units on a scale				
median (full range (min-max))				
median (full range)	-1 (-10 to 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Synovial fluid and proliferation at Week 52

End point title	Synovial fluid and proliferation at Week 52

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 52

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
median (full range (min-max))				
median (full range)	5 (0 to 16)			

Statistical analyses

No statistical analyses for this end point

Secondary: Synovial fluid and proliferation at Week 36

End point title	Synovial fluid and proliferation at Week 36

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 36

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
median (full range (min-max))				
median (full range)	5 (0 to 16)			

Statistical analyses

No statistical analyses for this end point

Secondary: Synovial fluid and proliferation at Week 24

End point title	Synovial fluid and proliferation at Week 24

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 24

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	5 (0 to 16)			

Statistical analyses

No statistical analyses for this end point

Secondary: Synovial fluid and proliferation at Week 12

End point title	Synovial fluid and proliferation at Week 12

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 12

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	5 (0 to 13)			

Statistical analyses

No statistical analyses for this end point

Secondary: Synovial fluid and proliferation at Week 8

End point title	Synovial fluid and proliferation at Week 8

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 8

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	5 (0 to 14)			

Statistical analyses

No statistical analyses for this end point

Secondary: Synovial fluid and proliferation at Week 6

End point title	Synovial fluid and proliferation at Week 6

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 6

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	6 (0 to 12)			

Statistical analyses

No statistical analyses for this end point

Secondary: Synovial fluid and proliferation at Week 4

End point title	Synovial fluid and proliferation at Week 4

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 4

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	6 (0 to 13)			

Statistical analyses

No statistical analyses for this end point

Secondary: Synovial fluid and proliferation at Week 2

End point title	Synovial fluid and proliferation at Week 2

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 2

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	63			
Units: units on a scale				
median (full range (min-max))				
median (full range)	7 (0 to 12)			

Statistical analyses

No statistical analyses for this end point

Secondary: Synovial fluid and proliferation at Week 1

End point title	Synovial fluid and proliferation at Week 1

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 1

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: units on a scale				
median (full range (min-max))				
median (full range)	7 (1 to 13)			

Statistical analyses

No statistical analyses for this end point

Secondary: Synovial fluid and proliferation at Week 0

End point title	Synovial fluid and proliferation at Week 0

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 0 (Baseline)

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: units on a scale				
median (full range (min-max))				
median (full range)	8 (0 to 15)			

Statistical analyses

No statistical analyses for this end point

Secondary: Doppler signal and blood flow at Week 52

End point title	Doppler signal and blood flow at Week 52

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 52

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (0 to 10)			

Statistical analyses

No statistical analyses for this end point

Secondary: Doppler signal and blood flow at Week 36

End point title	Doppler signal and blood flow at Week 36

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 36

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (0 to 10)			

Statistical analyses

No statistical analyses for this end point

Secondary: Doppler signal and blood flow at Week 24

End point title	Doppler signal and blood flow at Week 24

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 24

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (0 to 10)			

Statistical analyses

No statistical analyses for this end point

Secondary: Doppler signal and blood flow at Week 12

End point title	Doppler signal and blood flow at Week 12

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 12

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (0 to 12)			

Statistical analyses

No statistical analyses for this end point

Secondary: Doppler signal and blood flow at Week 8

End point title	Doppler signal and blood flow at Week 8

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 8

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0 (0 to 7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Doppler signal and blood flow at Week 6

End point title	Doppler signal and blood flow at Week 6

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 6

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	0.5 (0 to 7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Doppler signal and blood flow at Week 4

End point title	Doppler signal and blood flow at Week 4

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 4

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	2 (0 to 9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Doppler signal and blood flow at Week 2

End point title	Doppler signal and blood flow at Week 2

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 2

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	63			
Units: units on a scale				
median (full range (min-max))				
median (full range)	1 (0 to 11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Doppler signal and blood flow at Week 1

End point title	Doppler signal and blood flow at Week 1

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 1

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: units on a scale				
median (full range (min-max))				
median (full range)	1 (0 to 11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Doppler signal and blood flow at Week 0

End point title	Doppler signal and blood flow at Week 0

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 0 (Baseline)

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: units on a scale				
median (full range (min-max))				
median (full range)	2 (0 to 12)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cartilage damage at Week 52

End point title	Cartilage damage at Week 52

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 52

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
median (full range (min-max))				
median (full range)	4 (0 to 20)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cartilage damage at Week 36

End point title	Cartilage damage at Week 36

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 36

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
median (full range (min-max))				
median (full range)	5 (0 to 24)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cartilage damage at Week 24

End point title	Cartilage damage at Week 24

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 24

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	4.5 (0 to 19)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cartilage damage at Week 12

End point title	Cartilage damage at Week 12

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 12

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	5 (0 to 20)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cartilage damage at Week 8

End point title	Cartilage damage at Week 8

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 8

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	4.5 (0 to 20)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cartilage damage at Week 6

End point title	Cartilage damage at Week 6

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 6

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	63			
Units: units on a scale				
median (full range (min-max))				
median (full range)	4 (0 to 20)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cartilage damage at Week 4

End point title	Cartilage damage at Week 4

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 4

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	63			
Units: units on a scale				
median (full range (min-max))				
median (full range)	4 (0 to 20)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cartilage damage at Week 2

End point title	Cartilage damage at Week 2

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 2

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	61			
Units: units on a scale				
median (full range (min-max))				
median (full range)	4 (0 to 21)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cartilage damage at Week 1

End point title	Cartilage damage at Week 1

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 1

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	57			
Units: units on a scale				
median (full range (min-max))				
median (full range)	5 (0 to 21)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cartilage damage at Week 0

End point title	Cartilage damage at Week 0

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 0 (Baseline)

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	56			
Units: units on a scale				
median (full range (min-max))				
median (full range)	6 (0 to 21)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bone erosion at Week 52

End point title	Bone erosion at Week 52

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 52

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
median (full range (min-max))				
median (full range)	2 (0 to 10)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bone erosion at Week 36

End point title	Bone erosion at Week 36

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 36

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
median (full range (min-max))				
median (full range)	2 (0 to 11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bone erosion at Week 24

End point title	Bone erosion at Week 24

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 24

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	2 (0 to 11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bone erosion at Week 12

End point title	Bone erosion at Week 12

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 12

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	2 (0 to 10)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bone erosion at Week 8

End point title	Bone erosion at Week 8

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 8

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	2 (0 to 10)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bone erosion at Week 6

End point title	Bone erosion at Week 6

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 6

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	2 (0 to 10)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bone erosion at Week 4

End point title	Bone erosion at Week 4

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 4

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	2 (0 to 10)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bone erosion at Week 2

End point title	Bone erosion at Week 2

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 2

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	63			
Units: units on a scale				
median (full range (min-max))				
median (full range)	2 (0 to 15)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bone erosion at Week 1

End point title	Bone erosion at Week 1

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 1

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: units on a scale				
median (full range (min-max))				
median (full range)	2 (0 to 15)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bone erosion at Week 0

End point title	Bone erosion at Week 0

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 0 (Baseline)

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	60			
Units: units on a scale				
median (full range (min-max))				
median (full range)	2 (0 to 15)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 52

End point title	Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 52

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 52

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
median (full range (min-max))				
median (full range)	5 (0 to 26)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 36

End point title	Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 36

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 36

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
median (full range (min-max))				
median (full range)	6 (0 to 26)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 24

End point title	Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 24

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 24

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	6.5 (0 to 26)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 12

End point title	Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 12

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 12

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	7 (0 to 22)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 8

End point title	Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 8

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 8

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	6 (0 to 16)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler

Signal/Blood Flow at Week 6

End point title	Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 6

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 6

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	7 (0 to 16)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 4

End point title	Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 4

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 4

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	8 (0 to 18)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 2

End point title	Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 2

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 2

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	63			
Units: units on a scale				
median (full range (min-max))				
median (full range)	8 (0 to 23)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 1

End point title	Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 1

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 1

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: units on a scale				
median (full range (min-max))				
median (full range)	8 (1 to 23)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 0

End point title	Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 0

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

End point type	Secondary

End point timeframe:

Week 0 (Baseline)

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: units on a scale				
median (full range (min-max))				
median (full range)	10 (1 to 24)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 52

End point title	Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 52

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 52

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
median (full range (min-max))				
median (full range)	7 (0 to 38)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 36

End point title	Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 36

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 36

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
median (full range (min-max))				
median (full range)	8 (0 to 38)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 24

End point title	Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 24

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 24

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	10 (0 to 38)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 12

End point title	Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 12

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 12

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	9 (0 to 38)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 8

End point title	Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 8

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 8

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: units on a scale				
median (full range (min-max))				
median (full range)	9 (0 to 34)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 6

End point title	Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 6

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 6

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	63			
Units: units on a scale				
median (full range (min-max))				
median (full range)	8 (0 to 33)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 4

End point title	Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 4

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 4

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	63			
Units: units on a scale				
median (full range (min-max))				
median (full range)	8 (0 to 34)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 2

End point title	Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 2

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 2

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	61			
Units: units on a scale				
median (full range (min-max))				
median (full range)	10 (0 to 43)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the progression in the Doppler signal, cartilage damage and

bone erosion score at Week 1	
End point title	Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 1

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 1

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	57			
Units: units on a scale				
median (full range (min-max))				
median (full range)	10 (0 to 47)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 0	
End point title	Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 0

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

End point type	Secondary

End point timeframe:

Week 0 (Baseline)

End point values	Certolizumab pegol (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	55			
Units: units on a scale				
median (full range (min-max))				
mean (standard deviation)	12 (0 to 47)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment Emergent Adverse Events were reported from Baseline (Week 0) up to the Safety Follow-up Visit (Week 60).

Adverse event reporting additional description:

Adverse Events refer to the Safety Set (SS) which consists of all subjects who received at least one dose of study medication.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	Certolizumab pegol

Reporting group description:

Subjects will be treated for 52 weeks with Certolizumab Pegol (CZP) (administration every two weeks) in combination with Methotrexate (MTX) (administration weekly). Dosing regimen of CZP consists of 3 administrations of 400 mg at Weeks 0, 2 and 4 followed by 200 mg every other week up to and including Week 50.

Serious adverse events	Certolizumab pegol		
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 132 (12.12%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lobular breast carcinoma in situ			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Malignant melanoma in situ			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Non-Hodgkin's lymphoma			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			

Flushing			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Genital prolapse			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Sinus disorder			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			

Anosmia			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tremor			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Retroperitoneal lymphadenopathy			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Periorbital oedema			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urticaria			

subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Bladder prolapse			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder mass			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Haematuria			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchopneumonia			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Paratyphoid fever			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Endophthalmitis			
subjects affected / exposed	1 / 132 (0.76%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Certolizumab pegol		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 132 (23.48%)		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	7 / 132 (5.30%)		
occurrences (all)	7		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	9 / 132 (6.82%)		
occurrences (all)	18		
Infections and infestations			
Influenza			
subjects affected / exposed	15 / 132 (11.36%)		
occurrences (all)	16		
Bronchitis			
subjects affected / exposed	7 / 132 (5.30%)		
occurrences (all)	7		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 July 2011	Protocol Amendment 1, dated 07 Jul 2011, was implemented after the central ethics committee review of the initial protocol, when changes were deemed necessary for conduct of this study in Italy. This amendment occurred prior to inclusion of subjects. The following changes were made throughout the protocol: • Quality of Life assessments were altered (eg, removal of PRISM test, Euro QoL-5D changed to EQ-5D-3L). • Evaluation of healthcare use' was added as an exploratory objective (and accordingly was added in list of other efficacy variables and concomitant procedures). • Laboratory assessments were centralized, except for ESR, TB and urine pregnancy testing.
07 July 2011	• Safety reporting was updated, with extension of the follow up period from 30 days to 10 weeks, and clarification that a serious AE (SAE) or an AE leading to premature discontinuation from the study had to be followed up until it had resolved, stabilized or the Investigator no longer felt it was clinically significant; TB and ischemic cardiac events were added to AEs of interest list; the anticipated AE list was removed. • Biomarkers assessments were updated (Week 0 assessment changed to Week -2). • Immunological assessments were updated (Week -2 assessment deleted, and Weeks 0, 2, 6, 12, and 36 assessments added to text). • For pregnancy testing and x-ray assessment, previously missing text was added (to correspond with schedule). • An explanation was added that EQ-5D-3L dimensions scores, VAS actual scores, and healthcare resource utilization scores would be summarized using descriptive statistics. • Previously termed 'anticipated AEs' in Appendices were renamed 'predicted AEs,' and those for CZP added. • Inclusion criterion number 9 was changed from 'Subject is naïve or has received up to 1 prior anti-TNF therapy, which was not discontinued due to primary failure' to 'Subject is naïve to RA related biologics (eg, anti-TNF therapy). • Exclusion criteria numbers 13 to 17 regarding prior treatments were replaced with 'Subject has received previous RA related biologics therapy (eg, anti-TNF)'.
24 October 2011	Protocol Amendment 2, dated 24 Oct 2011, was implemented after the Sponsor discussed the subgroup analysis with other experts. It was decided to remove the MRI assessments: although the use of gadolinium would have resulted in better data, this invasive method could have been a limiting factor and restrict recruitment. Lack of interest in MRI assessments at investigational sites also contributed to this decision. It was agreed that remaining methods would still provide sufficient data to monitor the response of joint synovitis and to investigate the predictability of an early sonography response for long-term response. The MRI Assessment was therefore removed from all applicable sections. In addition, clarification was added that methotrexate should be taken throughout the study without discontinuation, and that no dose adjustment was allowed except for documented intolerance or toxicity. This amendment was approved after one subject had been screened.

06 March 2013	Protocol Amendment 3, dated 06 Mar 2013, was implemented after to clarify objectives and endpoints of the study, to add a second reading of US images for the purpose of assessing interreader variability, to align the protocol with UCB standards in terms of definitions, naming conventions, and procedures, and to streamline the planned data analysis in alignment with the objectives. Specifically: • The secondary objective was modified to allow for more general conclusions on the results of US assessments; assessment of the changes in CRP and ESR were replaced with assessment of the relationship between US response and clinical response over time. • Endpoints were shifted in the appropriate sections in alignment with the objectives; in particular, CRP and ESR were moved to the Other Efficacy section. • The procedure of the analysis of US images was amended to allow for an assessment of interobserver reliability. • Clarifications and definitions were added to specify the study conduct and procedures.
06 March 2013	• Definitions were updated to be consistent with UCB standards (eg, specifications of tuberculosis [TB] assessments and the TEAE definition). • Study timelines were amended according to new forecasts. • Rescreening of subjects was allowed for screen-failed subjects. The following additional changes were made throughout the protocol: • The upper limit of the category Low Disease Activity was changed from <3.2 to ≤3.2. • The definition of clinical response based on DAS28-ESR was changed from a reduction of >1.2 scores in the DAS28-ESR to a reduction of ≥1.2 scores in the DAS28-ESR. • The Health assessment questionnaire (HAQ) was renamed Health Assessment Questionnaire Disability Index (HAQ-DI). • The term Investigator's Assessment of Disease Activity (IGA) was changed to Physician's Assessment of Disease Activity (PhGADA). • The abbreviation of Patient's Assessment of Disease Activity (PGA) was changed to PtGADA. • The word parameter was replaced by the word variable. • HBV DNA requirements were clarified.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported