Clinical trial results:
A Multicenter Open-Label Study of Etanercept Withdrawal and Retreatment in Subjects With Non-Radiographic Axial Spondyloarthritis who Achieved Adequate 24 Week Response

Summary

EudraCT number	2015-000541-24
Trial protocol	DE FI BE PL HU SE ES NL CZ
Global end of trial date	06 September 2019

Results information

Result version number	v1
This version publication date	23 May 2020
First version publication date	23 May 2020

Trial information

Trial identification

Sponsor protocol code	B1801381

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	21 February 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 September 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To estimate the proportion of subjects who flare within 40 weeks following withdrawal of ETN in subjects who have achieved ASDAS CRP less than 1.3 (inactive disease)

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 September 2015
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	Australia: 27
Country: Number of subjects enrolled	Belgium: 5
Country: Number of subjects enrolled	Colombia: 7
Country: Number of subjects enrolled	Czech Republic: 17
Country: Number of subjects enrolled	Finland: 9
Country: Number of subjects enrolled	France: 2
Country: Number of subjects enrolled	Germany: 14
Country: Number of subjects enrolled	Hungary: 5
Country: Number of subjects enrolled	Netherlands: 4
Country: Number of subjects enrolled	Poland: 75
Country: Number of subjects enrolled	Spain: 11
Country: Number of subjects enrolled	Sweden: 7
Country: Number of subjects enrolled	Taiwan: 13
Country: Number of subjects enrolled	United States: 13
Worldwide total number of subjects	209
EEA total number of subjects	149

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)	209
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted in the 14 countries from 24 September 2015 to 20 September 2019. A total of 210 subjects were enrolled.

Pre-assignment

Screening details:

The first visit of the Period 3 (re-treatment period) might occur at the same time as a regularly scheduled visit during Period 2 (withdrawal period) or as an unscheduled visit for a subject who experienced flare during Period 2.

Period 1

Period 1 title	Induction Period (24 weeks)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Etanercept

Arm description:

All enrolled subjects with non-radiographic axial spondyloarthritis (nr-ax SpA) were treated for 24 weeks with 50-milligram (mg) weekly dose of Etanercept in Period 1 (Induction Period). Subjects who achieved ankylosing spondylitis disease activity scale(ASDAS) C-reactive protein (CRP) less than (<) 1.3 at Week 24 entered into Period 2 (Withdrawal Period). In this period, subjects discontinued Etanercept for 40 weeks and subjects who achieved an ASDAS erythrocyte sedimentation rate (ESR) level greater than or equal to (>=) 2.1 by Week 64, then entered into Period 3 (Retreatment Period) of 12 weeks, treated with 50 mg weekly doses, and then followed up until 28 days after last dose of Etanercept. Subjects who did not qualify for Period 2 or 3 were followed up until 28 days after last dose of Etanercept.

Arm type	Experimental
Investigational medicinal product name	Etanercept
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received Etanercept 50 mg weekly dose for 24 weeks.

Number of subjects in period 1	Etanercept
Started	209
Completed	188
Not completed	21
Consent withdrawn by subject	1
Adverse event, non-fatal	5
Unspecified	2
Eligibility Criteria	5
Lost to follow-up	1
Lack of efficacy	6

Protocol deviation	1

Period 2

Period 2 title	Withdrawal Period (40 weeks)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Etanercept

Arm description:

All enrolled subjects with non-radiographic axial spondyloarthritis (nr-ax SpA) were treated for 24 weeks with 50-milligram (mg) weekly dose of Etanercept in Period 1 (Induction Period). Subjects who achieved ankylosing spondylitis disease activity scale(ASDAS) C-reactive protein (CRP) less than (<) 1.3 at Week 24 entered into Period 2 (Withdrawal Period). In this period, subjects discontinued Etanercept for 40 weeks and subjects who achieved an ASDAS erythrocyte sedimentation rate (ESR) level greater than or equal to (>=) 2.1 by Week 64, then entered into Period 3 (Retreatment Period) of 12 weeks, treated with 50 mg weekly doses, and then followed up until 28 days after last dose of Etanercept. Subjects who did not qualify for Period 2 or 3 were followed up until 28 days after last dose of Etanercept.

Arm type	Experimental
Investigational medicinal product name	Etanercept
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects discontinued Etanercept in Period 2.

Number of subjects in period 2[1]	Etanercept
Started	119
Completed	112
Not completed	7
Consent withdrawn by subject	5
Protocol deviation	2

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Participants who completed Period 1 and achieved ASDAS-CRP<1.3 were eligible to enter into Period 2. Participants who completed Period 2 and achieved ASDAS-ESR>=2.1 were eligible to

enter into Period 3.

Period 3

Period 3 title	Retreatment Period (12 weeks)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Etanercept

Arm description:

All enrolled subjects with non-radiographic axial spondyloarthritis (nr-ax SpA) were treated for 24 weeks with 50-milligram (mg) weekly dose of Etanercept in Period 1 (Induction Period). Subjects who achieved ankylosing spondylitis disease activity scale(ASDAS) C-reactive protein (CRP) less than (<) 1.3 at Week 24 entered into Period 2 (Withdrawal Period). In this period, subjects discontinued Etanercept for 40 weeks and subjects who achieved an ASDAS erythrocyte sedimentation rate (ESR) level greater than or equal to (>=) 2.1 by Week 64, then entered into Period 3 (Retreatment Period) of 12 weeks, treated with 50 mg weekly doses, and then followed up until 28 days after last dose of Etanercept. Subjects who did not qualify for Period 2 or 3 were followed up until 28 days after last dose of Etanercept.

Arm type	Experimental
Investigational medicinal product name	Etanercept
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received Etanercept 50 mg weekly dose for 12 weeks.

Number of subjects in period 3[2]	Etanercept
Started	87
Completed	84
Not completed	3
Consent withdrawn by subject	2
Lost to follow-up	1

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Participants who completed Period 1 and achieved ASDAS-CRP<1.3 were eligible to enter into Period 2. Participants who completed Period 2 and achieved ASDAS-ESR>=2.1 were eligible to enter into Period 3.

Baseline characteristics

Reporting groups	
Reporting group title	Etanercept

Reporting group description:

All enrolled subjects with non-radiographic axial spondyloarthritis (nr-ax SpA) were treated for 24 weeks with 50-milligram (mg) weekly dose of Etanercept in Period 1 (Induction Period). Subjects who achieved ankylosing spondylitis disease activity scale(ASDAS) C-reactive protein (CRP) less than (<) 1.3 at Week 24 entered into Period 2 (Withdrawal Period). In this period, subjects discontinued Etanercept for 40 weeks and subjects who achieved an ASDAS erythrocyte sedimentation rate (ESR) level greater than or equal to (>=) 2.1 by Week 64, then entered into Period 3 (Retreatment Period) of 12 weeks, treated with 50 mg weekly doses, and then followed up until 28 days after last dose of Etanercept. Subjects who did not qualify for Period 2 or 3 were followed up until 28 days after last dose of Etanercept.

Reporting group values	Etanercept	Total	
Number of subjects	209	209	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	209	209	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous Units: Years			
arithmetic mean	33.1		
standard deviation	± 8.21	-	
Sex: Female, Male Units: Subjects			
Female	97	97	
Male	112	112	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	14	14	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	1	1	
White	186	186	
More than one race	0	0	
Unknown or Not Reported	8	8	

End points

End points reporting groups

Reporting group title	Etanercept

Reporting group description:

All enrolled subjects with non-radiographic axial spondyloarthritis (nr-ax SpA) were treated for 24 weeks with 50-milligram (mg) weekly dose of Etanercept in Period 1 (Induction Period). Subjects who achieved ankylosing spondylitis disease activity scale(ASDAS) C-reactive protein (CRP) less than (<) 1.3 at Week 24 entered into Period 2 (Withdrawal Period). In this period, subjects discontinued Etanercept for 40 weeks and subjects who achieved an ASDAS erythrocyte sedimentation rate (ESR) level greater than or equal to (>=) 2.1 by Week 64, then entered into Period 3 (Retreatment Period) of 12 weeks, treated with 50 mg weekly doses, and then followed up until 28 days after last dose of Etanercept. Subjects who did not qualify for Period 2 or 3 were followed up until 28 days after last dose of Etanercept.

Reporting group title	Etanercept

Reporting group description:

All enrolled subjects with non-radiographic axial spondyloarthritis (nr-ax SpA) were treated for 24 weeks with 50-milligram (mg) weekly dose of Etanercept in Period 1 (Induction Period). Subjects who achieved ankylosing spondylitis disease activity scale(ASDAS) C-reactive protein (CRP) less than (<) 1.3 at Week 24 entered into Period 2 (Withdrawal Period). In this period, subjects discontinued Etanercept for 40 weeks and subjects who achieved an ASDAS erythrocyte sedimentation rate (ESR) level greater than or equal to (>=) 2.1 by Week 64, then entered into Period 3 (Retreatment Period) of 12 weeks, treated with 50 mg weekly doses, and then followed up until 28 days after last dose of Etanercept. Subjects who did not qualify for Period 2 or 3 were followed up until 28 days after last dose of Etanercept.

Reporting group title	Etanercept

Reporting group description:

All enrolled subjects with non-radiographic axial spondyloarthritis (nr-ax SpA) were treated for 24 weeks with 50-milligram (mg) weekly dose of Etanercept in Period 1 (Induction Period). Subjects who achieved ankylosing spondylitis disease activity scale(ASDAS) C-reactive protein (CRP) less than (<) 1.3 at Week 24 entered into Period 2 (Withdrawal Period). In this period, subjects discontinued Etanercept for 40 weeks and subjects who achieved an ASDAS erythrocyte sedimentation rate (ESR) level greater than or equal to (>=) 2.1 by Week 64, then entered into Period 3 (Retreatment Period) of 12 weeks, treated with 50 mg weekly doses, and then followed up until 28 days after last dose of Etanercept. Subjects who did not qualify for Period 2 or 3 were followed up until 28 days after last dose of Etanercept.

Subject analysis set title	Etanercept: Period 1
Subject analysis set type	Full analysis

Subject analysis set description:

All enrolled subjects with nr-ax SpA were treated for 24 weeks with 50 milligram weekly dose of Etanercept in Period 1 (Induction Period). Subjects who did not qualify for Period 2 were followed up until 28 days after last dose of Etanercept.

Subject analysis set title	Etanercept: Period 2
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects who achieved ASDAS CRP less than 1.3 at Week 24 then entered into Period 2 (Withdrawal Period). In this period, subjects discontinued Etanercept for 40 weeks (from Week 24 to Week 64). Subjects who did not qualify for Period 2 were followed up until 28 days after last dose of Etanercept.

Subject analysis set title	Etanercept: Period 3
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects who achieved an ASDAS ESR level >= 2.1 by Week 64, then entered into Period 3 (Retreatment Period) of 12 weeks, treated with 50 mg weekly doses, and then followed up until 28 days after last dose of Etanercept.

Primary: Percentage of Subjects Who Experienced Flare Within 40 Weeks Following Withdrawal of 24 Weeks of Etanercept Treatment

End point title	Percentage of Subjects Who Experienced Flare Within 40 Weeks Following Withdrawal of 24 Weeks of Etanercept Treatment[1]

End point description:

Subjects who experienced ASDAS-Erythrocyte Sedimentation Rate (ESR) level of >=2.1 were defined as

being flared. ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0 = no disease activity and 10= high disease activity. CRP measured in milligram per liter (mg/L) and ESR measured in millimeter per hour (mm/hr). Percentage of subjects who flared within 40 weeks after the withdrawal of Etanercept treatment of 24 weeks in Induction period are reported in this outcome measure. Full analysis set for period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed last observation carried forward (LOCF).

End point type	Primary

End point timeframe:

Within 40 weeks after Etanercept withdrawal (from Week 24 to Week 64)

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: Only descriptive data was planned to be analysed for this endpoint

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)	74.8 (66.30 to 82.04)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Flare Following Withdrawal of Etanercept Treatment

End point title	Time to Flare Following Withdrawal of Etanercept Treatment

End point description:

Subjects who experienced ASDAS-ESR level of >=2.1 were defined as being flared. Time to experience flare in subjects was defined as time to achieve ASDAS-ESR level of >=2.1 after the withdrawal of Etanercept treatment of 24 weeks in Induction period. ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0 = no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. Full analysis set for period 2 included all subjects who had at least one evaluation during period 2.

End point type	Secondary

End point timeframe:

Within 40 weeks after Etanercept withdrawal (from Week 24 to Week 64)

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: weeks				
median (confidence interval 95%)	16.1 (12.57 to 24.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Less Than (<)1.3: Observed Cases (OC): Period 1

End point title	Percentage of Subjects With Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Less Than (<)1.3: Observed Cases (OC): Period 1

End point description:

ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. ASDAS ranged as inactive disease: 0 <= ASDAS-CRP <1.3; moderate disease activity: 1.3 <= ASDAS-CRP <2.1; high disease activity: 2.1 <= ASDAS-CRP <=3.5; very high disease activity: 3.5 < ASDAS-CRP. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Baseline (n=206)	0.5 (0.05 to 2.25)			
Week 4 (n=208)	14.4 (10.15 to 19.68)			
Week 8 (n=201)	27.4 (21.55 to 33.82)			
Week 12 (n=197)	38.1 (31.50 to 44.99)			
Week 16 (n=191)	41.9 (35.05 to 48.96)			
Week 24 (n=190)	62.6 (55.60 to 69.28)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Less Than (<)1.3: Observed Cases (OC): Period 2

End point title	Percentage of Subjects With Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Less Than (<)1.3: Observed Cases (OC): Period 2

End point description:

ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. ASDAS ranged as inactive disease: 0 <= ASDAS-CRP <1.3; moderate disease activity: 1.3 <= ASDAS-CRP <2.1; high disease activity: 2.1 <= ASDAS-CRP <=3.5; very high disease activity: 3.5 < ASDAS-CRP. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 28 (n=110)	52.7 (43.43 to 61.89)			
Week 32 (n=93)	45.2 (35.32 to 55.29)			
Week 40 (n=66)	48.5 (36.71 to 60.39)			
Week 48 (n=50)	42.0 (29.09 to 55.81)			
Week 56 (n=41)	56.1 (40.93 to 70.44)			
Week 64 (n=34)	55.9 (39.28 to 71.53)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Less Than (<)1.3: Observed Cases (OC): Period 3

End point title	Percentage of Subjects With Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Less Than (<)1.3: Observed Cases (OC): Period 3

End point description:

ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. ASDAS ranged as inactive disease: 0 <= ASDAS-CRP <1.3; moderate disease activity: 1.3 <= ASDAS-CRP <2.1; high disease activity: 2.1 <=

ASDAS-CRP <=3.5; very high disease activity: 3.5 < ASDAS-CRP. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 68 (n=84)	53.6 (42.94 to 63.96)			
Week 72 (n=86)	61.6 (51.10 to 71.38)			
Week 76 (n=85)	62.4 (51.78 to 72.10)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Less Than (<) 1.3: Last Observation Carried Forward (LOCF): Period 1

End point title	Percentage of Subjects With Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Less Than (<) 1.3: Last Observation Carried Forward (LOCF): Period 1

End point description:

ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. ASDAS ranged as inactive disease: 0 <= ASDAS-CRP <1.3; moderate disease activity: 1.3 <= ASDAS-CRP <2.1; high disease activity: 2.1 <= ASDAS-CRP <=3.5; very high disease activity: 3.5 < ASDAS-CRP. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Baseline (n=209)	0.5 (0.05 to 2.25)			
Week 4 (n=208)	14.4 (10.15 to 19.68)			
Week 8 (n=208)	27.4 (21.68 to 33.75)			
Week 12 (n=208)	36.5 (30.22 to 43.23)			
Week 16 (n=208)	40.4 (33.89 to 47.15)			
Week 24 (n=208)	58.7 (51.88 to 65.19)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Less Than (<) 1.3: Last Observation Carried Forward (LOCF): Period 2

End point title	Percentage of Subjects With Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Less Than (<) 1.3: Last Observation Carried Forward (LOCF): Period 2

End point description:

ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. ASDAS ranged as inactive disease: 0 <= ASDAS-CRP <1.3; moderate disease activity: 1.3 <= ASDAS-CRP <2.1; high disease activity: 2.1 <= ASDAS-CRP <=3.5; very high disease activity: 3.5 < ASDAS-CRP. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 28 (n=110)	52.7 (43.43 to 61.89)			
Week 32 (n=113)	39.8 (31.15 to 49.01)			

Week 40 (n=113)	34.5 (26.23 to 43.58)			
Week 48 (n=113)	26.5 (19.07 to 35.21)			
Week 56 (n=113)	29.2 (21.42 to 38.03)			
Week 64 (n=113)	24.8 (17.52 to 33.31)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Less Than (<) 1.3: Last Observation Carried Forward (LOCF): Period 3

End point title	Percentage of Subjects With Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Less Than (<) 1.3: Last Observation Carried Forward (LOCF): Period 3

End point description:

ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. ASDAS ranged as inactive disease: 0 <= ASDAS-CRP <1.3; moderate disease activity: 1.3 <= ASDAS-CRP <2.1; high disease activity: 2.1 <= ASDAS-CRP <=3.5; very high disease activity: 3.5 < ASDAS-CRP Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 68 (n=85)	52.9 (42.38 to 63.31)			
Week 72 (n=87)	60.9 (50.45 to 70.68)			
Week 76 (n=87)	62.1 (51.61 to 71.74)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS 20) Response: Observed Cases (OC): Period 1

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS 20) Response: Observed Cases (OC): Period 1

End point description:

ASAS measures symptomatic improvement in AS in 4 domains: subject global assessment of disease activity, total back pain, function (from [Bath Ankylosing Spondylitis Functional Index] BASFI) and inflammation (from [Bath Ankylosing Spondylitis Disease Activity Index] BASDAI). ASAS 20 responders: subjects with at least 20% improvement from baseline in disease activity and an absolute change of at least 1 unit on a 0 to 10 cm scale (0=no disease activity; 10=high disease activity, where higher scores indicated higher disease activity) in 3 or more domains, and no worsening of >=20% and absolute change 1 unit in the remaining domain. All 4 domains were measured on a 0-100 mm scale (0= no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). These scores were then converted to 0-10 cm scale for assessment of ASAS 20. FAS for Period 1 analysed. Here, "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 4 (n=208)	58.7 (51.88 to 65.19)			
Week 8 (n=201)	68.7 (62.01 to 74.77)			
Week 12 (n=198)	71.7 (65.16 to 77.64)			
Week 16 (n=192)	78.1 (71.88 to 83.52)			
Week 24 (n=190)	85.8 (80.30 to 90.20)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS 20) Response: Observed Cases (OC): Period 2

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS 20) Response: Observed Cases (OC): Period 2

End point description:

ASAS measures symptomatic improvement in AS in 4 domains: subject global assessment of disease activity, total back pain, function (from BASFI) and inflammation (from BASDAI). ASAS 20 responders were defined as subjects with at least 20% improvement from baseline in disease activity and an absolute change of at least 1 unit on a 0 to 10 cm scale (0=no disease activity; 10=high disease activity, where higher scores indicated higher disease activity) in 3 or more domains, and no worsening of >=20% and absolute change 1 unit in the remaining domain. All 4 domains were measured on a 0-100 millimeter (mm) scale (0= no disease activity; 100 = high disease activity, where higher scores

indicated higher disease activity). These scores were then converted to 0-10 cm scale for assessment of ASAS 20. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 28 (n=100)	86.0 (78.21 to 91.74)			
Week 32 (n=81)	88.9 (80.71 to 94.36)			
Week 40 (n=59)	83.1 (72.02 to 90.94)			
Week 48 (n=47)	91.5 (81.02 to 97.06)			
Week 56 (n=35)	91.4 (78.86 to 97.53)			
Week 64 (n=27)	92.6 (78.30 to 98.43)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS 20) Response: Observed Cases (OC): Period 3

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS 20) Response: Observed Cases (OC): Period 3

End point description:

ASAS measures symptomatic improvement in AS in 4 domains: subject global assessment of disease activity, total back pain, function (from BASFI) and inflammation (from BASDAI). ASAS 20 responders were defined as subjects with at least 20% improvement from baseline in disease activity and an absolute change of at least 1 unit on a 0 to 10 cm scale (0=no disease activity; 10=high disease activity, where higher scores indicated higher disease activity) in 3 or more domains, and no worsening of >=20% and absolute change 1 unit in the remaining domain. All 4 domains were measured on a 0-100 millimeter (mm) scale (0= no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). These scores were then converted to 0-10 cm scale for assessment of ASAS 20. Full analysis set analyzed. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	33.3 (14.03 to 58.42)			
Week 68 (n=85)	80.0 (70.58 to 87.42)			
Week 72 (n=87)	81.6 (72.51 to 88.65)			
Week 76 (n=85)	87.1 (78.72 to 92.93)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS 20) Response: Last Observation Carried Forward (LOCF): Period 1

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS 20) Response: Last Observation Carried Forward (LOCF): Period 1

End point description:

ASAS measures symptomatic improvement in AS in 4 domains: subject global assessment of disease activity, total back pain, function (from BASFI) and inflammation (from BASDAI). ASAS 20 responders: subjects with at least 20% improvement from baseline in disease activity and an absolute change of at least 1 unit on a 0 to 10 cm scale (0=no disease activity; 10=high disease activity, where higher scores indicated higher disease activity) in 3 or more domains, and no worsening of >=20% and absolute change 1 unit in the remaining domain. All 4 domains were measured on a 0-100 mm scale (0= no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). These scores were then converted to 0-10 cm scale for assessment of ASAS 20. FAS for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF.

End point type	Secondary

End point timeframe:

Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	208			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 4	58.7 (51.88 to 65.19)			
Week 8	68.8 (62.23 to 74.76)			
Week 12	71.2 (64.74 to 76.99)			
Week 16	76.4 (70.34 to 81.82)			

Week 24	83.2 (77.65 to 87.78)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS 20) Response: Last Observation Carried Forward (LOCF): Period 2

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS 20) Response: Last Observation Carried Forward (LOCF): Period 2

End point description:

ASAS measures symptomatic improvement in AS in 4 domains: subject global assessment of disease activity, total back pain, function (from BASFI) and inflammation (from BASDAI). ASAS 20 responders: subjects with at least 20% improvement from baseline in disease activity and an absolute change of at least 1 unit on a 0 to 10 cm scale (0=no disease activity; 10=high disease activity, where higher scores indicated higher disease activity) in 3 or more domains, and no worsening of >=20% and absolute change 1 unit in the remaining domain. All 4 domains were measured on a 0-100 mm scale (0= no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). These scores were then converted to 0-10 cm scale for assessment of ASAS 20. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 28 (n=100)	86.0 (78.21 to 91.74)			
Week 32 (n=102)	84.3 (76.34 to 90.37)			
Week 40 (n=102)	79.4 (70.81 to 86.37)			
Week 48 (n=102)	79.4 (70.81 to 86.37)			
Week 56 (n=102)	78.4 (69.73 to 85.55)			
Week 64 (n=102)	77.5 (68.65 to 84.72)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS 20) Response: Last Observation Carried Forward (LOCF): Period 3

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS 20) Response: Last Observation Carried Forward (LOCF): Period 3

End point description:

ASAS measures symptomatic improvement in AS in 4 domains: subject global assessment of disease activity, total back pain, function (from BASFI) and inflammation (from BASDAI). ASAS 20 responders: subjects with at least 20% improvement from baseline in disease activity and an absolute change of at least 1 unit on a 0 to 10 cm scale (0=no disease activity; 10=high disease activity, where higher scores indicated higher disease activity) in 3 or more domains, and no worsening of >=20% and absolute change 1 unit in the remaining domain. All 4 domains measured on 0-100 mm scale (0= no disease activity; 100 = high disease activity, higher scores indicated higher disease activity). These scores were then converted to 0-10 cm scale for assessment of ASAS 20. FAS Period 3: all subjects who took study retreatment medication and had at least 1 evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	33.3 (14.03 to 58.42)			
Week 68 (n=86)	79.1 (69.60 to 86.62)			
Week 72 (n=87)	81.6 (72.51 to 88.65)			
Week 76 (n=87)	86.2 (77.82 to 92.23)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society 40 (ASAS 40) Response: Last Observation Carried Forward (LOCF): Period 1

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society 40 (ASAS 40) Response: Last Observation Carried Forward (LOCF): Period 1

End point description:

ASAS measures symptomatic improvement in AS in 4 domains: subject global assessment of disease activity, total back pain, function (from BASFI) and inflammation (from BASDAI). ASAS 40 responders: subjects with at least 40% and absolute improvement of at least 2 units on a 0 to 10 cm scale (converted from 0 to 100 mm) or an improvement of 100% for those domains that have a baseline score <2 in at least 3 of the 4 domains: subject assessment of disease activity, mean of subjects assessment of total back pain, function represented by the BASFI score, inflammation represented by

the mean of the two morning stiffness-related BASDAI scores. No worsening at all in any of the domains. Each domain was measured on a 0-100 mm scale (0=no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). These scores were then converted to 0-10 cm scale for assessment of ASAS 40.FAS Period 1 population. Missing data was imputed using mixed LOCF.

End point type	Secondary

End point timeframe:

Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	208			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 4	34.6 (28.40 to 41.26)			
Week 8	49.0 (42.30 to 55.81)			
Week 12	51.0 (44.19 to 57.70)			
Week 16	61.1 (54.32 to 67.49)			
Week 24	71.6 (65.24 to 77.43)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society 40 (ASAS 40) Response: Last Observation Carried Forward (LOCF): Period 2

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society 40 (ASAS 40) Response: Last Observation Carried Forward (LOCF): Period 2

End point description:

ASAS measures symptomatic improvement in AS in 4 domains: subject global assessment of disease activity, total back pain, function. ASAS 40 responders: subjects with at least 40% and absolute improvement of at least 2 units on a 0 to 10 cm scale (converted from 0 to 100 mm) or an improvement of 100% for those domains that have a baseline score <2 in at least 3 of the 4 domains: subject assessment of disease activity, mean of subjects assessment of total back pain, function represented by the BASFI score, inflammation represented by the mean of the two morning stiffness-related BASDAI scores. No worsening at all in any of the domains. Each domain was measured on a 0-100 mm scale (0=no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). These scores were then converted to 0-10 cm scale for assessment of ASAS 40.FAS Period 2 population. Missing data was imputed using mixed LOCF."n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 28 (n=100)	77.0 (68.06 to 84.40)			
Week 32 (n=102)	72.5 (63.35 to 80.49)			
Week 40 (n=102)	69.6 (60.23 to 77.89)			
Week 48 (n=102)	64.7 (55.12 to 73.47)			
Week 56 (n=102)	66.7 (57.15 to 75.25)			
Week 64 (n=102)	62.7 (53.11 to 71.67)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society 40 (ASAS 40) Response: Last Observation Carried Forward (LOCF): Period 3

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society 40 (ASAS 40) Response: Last Observation Carried Forward (LOCF): Period 3

End point description:

ASAS measures symptomatic improvement in AS in 4 domains: subject global assessment of disease activity, total back pain, function. ASAS 40 responders: subjects with at least 40% and absolute improvement of at least 2 units on a 0 to 10 cm scale (converted from 0 to 100 mm) or an improvement of 100% for those domains that have a baseline score <2 in at least 3 of the 4 domains: subject assessment of disease activity, mean of subjects assessment of total back pain, function represented by the BASFI score, inflammation represented by the mean of the two morning stiffness-related BASDAI scores. No worsening at all in any of the domains. Each domain was measured on a 0-100 mm scale (0=no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). These scores were then converted to 0-10 cm scale for assessment of ASAS 40.FAS Period 3 population. Missing data was imputed using mixed LOCF. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	20.0 (5.98 to 44.36)			
Week 68 (n=86)	67.4 (57.09 to 76.64)			

Week 72 (n=87)	74.7 (64.88 to 82.94)			
Week 76 (n=87)	77.0 (67.38 to 84.88)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society 40 (ASAS 40) Response: Observed Cases (OC): Period 1

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society 40 (ASAS 40) Response: Observed Cases (OC): Period 1

End point description:

ASAS measures symptomatic improvement in AS in 4 domains: subject global assessment of disease activity, total back pain, function. ASAS 40 responders: subjects with at least 40% and absolute improvement of at least 2 units on a 0 to 10 cm scale (converted from 0 to 100 mm) or an improvement of 100% for those domains that have a baseline score <2 in at least 3 of the 4 domains: subject assessment of disease activity, mean of subjects assessment of total back pain, function represented by the BASFI score, inflammation represented by the mean of the two morning stiffness-related BASDAI scores. No worsening at all in any of the domains. Each domain was measured on a 0-100 mm scale (0=no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). These scores were then converted to 0-10 cm scale for assessment of ASAS 40. FAS Period 1 population. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 4 (n=208)	34.6 (28.40 to 41.26)			
Week 8 (n=201)	49.3 (42.39 to 56.13)			
Week 12 (n=198)	52.5 (45.58 to 59.40)			
Week 16 (n=192)	64.1 (57.11 to 70.60)			
Week 24 (n=190)	75.8 (69.34 to 81.46)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society 40 (ASAS 40) Response: Observed Cases (OC): Period 2

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society 40 (ASAS 40) Response: Observed Cases (OC): Period 2

End point description:

ASAS measures symptomatic improvement in AS in 4 domains: subject global assessment of disease activity, total back pain, function. ASAS 40 responders: subjects with at least 40% and absolute improvement of at least 2 units on a 0 to 10 cm scale (converted from 0 to 100 mm) or an improvement of 100% for those domains that have a baseline score <2 in at least 3 of the 4 domains: subject assessment of disease activity, mean of subjects assessment of total back pain, function represented by the BASFI score, inflammation represented by the mean of the two morning stiffness-related BASDAI scores. No worsening at all in any of the domains. Each domain was measured on a 0-100 mm scale (0=no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). These scores were then converted to 0-10 cm scale for assessment of ASAS 40. FAS Period 2 population. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 28 (n=100)	77.0 (68.06 to 84.40)			
Week 32 (n=81)	77.8 (67.85 to 85.76)			
Week 40 (n=59)	74.6 (62.48 to 84.33)			
Week 48 (n=47)	74.5 (60.81 to 85.22)			
Week 56 (n=35)	82.9 (68.03 to 92.51)			
Week 64 (n=27)	74.1 (55.71 to 87.58)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society 40 (ASAS 40) Response: Observed Cases (OC): Period 3

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society 40 (ASAS 40) Response: Observed Cases (OC): Period 3

End point description:

ASAS measures symptomatic improvement in AS in 4 domains: subject global assessment of disease activity, total back pain, function. ASAS 40 responders: subjects with at least 40% and absolute improvement of at least 2 units on a 0 to 10 cm scale (converted from 0 to 100 mm) or an improvement of 100% for those domains that have a baseline score <2 in at least 3 of the 4 domains: subject assessment of disease activity, mean of subjects assessment of total back pain, function represented by

the BASFI score, inflammation represented by the mean of the two morning stiffness-related BASDAI scores. No worsening at all in any of the domains. Each domain was measured on a 0-100 mm scale (0=no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). These scores were then converted to 0-10 cm scale for assessment of ASAS 40. FAS Period 3 population. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	20.0 (5.98 to 44.36)			
Week 68 (n=85)	68.2 (57.86 to 77.40)			
Week 72 (n=87)	74.7 (64.88 to 82.94)			
Week 76 (n=85)	78.8 (69.27 to 86.46)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS) Partial Remission: Last Observation Carried Forward (LOCF): Period 1

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS) Partial Remission: Last Observation Carried Forward (LOCF): Period 1

End point description:

ASAS partial remission was defined as a score of 2 units or less (on a scale of 0-10 cm, where 0 = no disease activity and 10 = high disease activity) in each of the 4 domains of ASAS: subject global assessment of disease activity, total back pain, function (from BASFI) and inflammation (from BASDAI). Each domain was measured on a 0-100 mm scale (0=no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). Reported values were then converted into cm for analysis. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF.

End point type	Secondary

End point timeframe:

Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	208			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 4	19.2 (14.32 to 24.99)			
Week 8	29.8 (23.90 to 36.27)			
Week 12	37.0 (30.67 to 43.72)			
Week 16	40.9 (34.35 to 47.63)			
Week 24	58.2 (51.39 to 64.73)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS) Partial Remission: Last Observation Carried Forward (LOCF): Period 2

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS) Partial Remission: Last Observation Carried Forward (LOCF): Period 2

End point description:

ASAS partial remission was defined as a score of 2 units or less (on a scale of 0-10 cm, where 0 = no disease activity and 10 = high disease activity) in each of the 4 domains of ASAS: subject global assessment of disease activity, total back pain, function (from BASFI) and inflammation (from BASDAI). Each domain was measured on a 0-100 mm scale (0=no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). Reported values were then converted into cm for analysis. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2.Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 28 (n=100)	63.0 (53.28 to 71.98)			
Week 32 (n=102)	53.9 (44.25 to 63.37)			
Week 40 (n=102)	48.0 (38.51 to 57.68)			

Week 48 (n=102)	41.2 (31.98 to 50.86)			
Week 56 (n=102)	44.1 (34.76 to 53.81)			
Week 64 (n=102)	41.2 (31.98 to 50.86)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS) Partial Remission: Last Observation Carried Forward (LOCF): Period 3

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS) Partial Remission: Last Observation Carried Forward (LOCF): Period 3

End point description:

ASAS partial remission was defined as a score of 2 units or less (on a scale of 0-10 cm, where 0 = no disease activity and 10 = high disease activity) in each of the 4 domains of ASAS: subject global assessment of disease activity, total back pain, function (from BASFI) and inflammation (from BASDAI). Each domain was measured on a 0-100 mm scale (0=no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). Reported values were then converted into cm for analysis. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	0.0 (0.00 to 15.18)			
Week 68 (n=86)	45.3 (35.13 to 55.88)			
Week 72 (n=87)	55.2 (44.70 to 65.31)			
Week 76 (n=87)	52.9 (42.43 to 63.13)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis

Society (ASAS) Partial Remission: Observed Cases (OC): Period 1

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS) Partial Remission: Observed Cases (OC): Period 1

End point description:

ASAS partial remission was defined as a score of 2 units or less (on a scale of 0-10 cm, where 0 = no disease activity and 10 = high disease activity) in each of the 4 domains of ASAS: subject global assessment of disease activity, total back pain, function (from BASFI) and inflammation (from BASDAI). Each domain was measured on a 0-100 mm scale (0=no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). Reported values were then converted into cm for analysis. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 4 (n=208)	19.2 (14.32 to 24.99)			
Week 8 (n=201)	30.3 (24.31 to 36.95)			
Week 12 (n=198)	38.9 (32.30 to 45.80)			
Week 16 (n=192)	42.7 (35.86 to 49.77)			
Week 24 (n=190)	62.1 (55.07 to 68.78)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS) Partial Remission: Observed Cases (OC): Period 2

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS) Partial Remission: Observed Cases (OC): Period 2

End point description:

ASAS partial remission was defined as a score of 2 units or less (on a scale of 0-10 cm, where 0 = no disease activity and 10 = high disease activity) in each of the 4 domains of ASAS: subject global assessment of disease activity, total back pain, function (from BASFI) and inflammation (from BASDAI). Each domain was measured on a 0-100 mm scale (0=no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). Reported values were then converted into cm for analysis. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 28 (n=100)	63.0 (53.28 to 71.98)			
Week 32 (n=81)	58.0 (47.15 to 68.34)			
Week 40 (n=59)	59.3 (46.59 to 71.16)			
Week 48 (n=47)	51.1 (37.07 to 64.93)			
Week 56 (n=35)	68.6 (52.20 to 82.02)			
Week 64 (n=27)	70.4 (51.75 to 84.88)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS) Partial Remission: Observed Cases (OC): Period 3

End point title	Percentage of Subjects Who Achieved Assessment of Spondyloarthritis Society (ASAS) Partial Remission: Observed Cases (OC): Period 3

End point description:

ASAS partial remission was defined as a score of 2 units or less (on a scale of 0-10 cm, where 0 = no disease activity and 10 = high disease activity) in each of the 4 domains of ASAS: subject global assessment of disease activity, total back pain, function (from BASFI) and inflammation (from BASDAI). Each domain was measured on a 0-100 mm scale (0=no disease activity; 100 = high disease activity, where higher scores indicated higher disease activity). Reported values were then converted into cm for analysis. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	0.0 (0.00 to 15.18)			

Week 68 (n=85)	45.9 (35.57 to 56.47)			
Week 72 (n=87)	55.2 (44.70 to 65.31)			
Week 76 (n=85)	52.9 (42.38 to 63.31)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS)-C-Reactive Protein (CRP) Score: Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS)-C-Reactive Protein (CRP) Score: Last Observation Carried Forward (LOCF): Period 1

End point description:

ASDAS: score combining assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on VAS ranging 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. ASDAS ranged as inactive disease: 0<= ASDAS-CRP <1.3; moderate disease activity: 1.3<= ASDAS-CRP <2.1; high disease activity: 2.1<= ASDAS-CRP <=3.5; very high disease activity: 3.5< ASDAS-CRP. The ASDAS-CRP is calculated with the following equation: 0.121*total back pain+0.110*subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln(CRP+1), Ln represents the natural logarithm. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=209)	3.54 (± 0.87)			
Change at week 4 (n=208)	-1.27 (± 1.02)			
Change at week 8 (n=208)	-1.53 (± 1.09)			
Change at week 12 (n=208)	-1.62 (± 1.15)			
Change at week 16 (n=208)	-1.77 (± 1.13)			
Change at week 24 (n=208)	-2.02 (± 1.15)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS)-C-Reactive Protein (CRP) Score: Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS)-C-Reactive Protein (CRP) Score: Last Observation Carried Forward (LOCF): Period 2

End point description:

ASDAS: score combining assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on VAS ranging 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. ASDAS ranged as inactive disease: 0<= ASDAS-CRP <1.3; moderate disease activity: 1.3<= ASDAS-CRP <2.1; high disease activity: 2.1<= ASDAS-CRP <=3.5; very high disease activity: 3.5< ASDAS-CRP. The ASDAS-CRP is calculated with the following equation: 0.121*total back pain+0.110*subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln(CRP+1), Ln represents the natural logarithm. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.90 (± 0.20)			
Change at Week 28 from Period 1 Baseline (n=110)	-1.83 (± 1.14)			
Change at Week 28 from Period 2 Baseline (n=110)	0.66 (± 0.89)			
Change at Week 32 from Period 1 Baseline (n=113)	-1.54 (± 1.17)			
Change at Week 32 from Period 2 Baseline(n=113)	0.96 (± 1.03)			
Change at Week 40 from Period 1 Baseline (n=113)	-1.36 (± 1.18)			
Change at Week 40 from Period 2 Baseline (n=113)	1.14 (± 1.07)			
Change at Week 48 from Period 1 Baseline (n=113)	-1.22 (± 1.18)			
Change at Week 48 from Period 2 Baseline(n=113)	1.29 (± 1.06)			
Change at Week 56 from Period 1 Baseline (n=113)	-1.17 (± 1.18)			
Change at Week 56 from Period 2 Baseline(n=113)	1.34 (± 1.07)			
Change at Week 64 from Period 1 Baseline (n=113)	-1.05 (± 1.16)			
Change at Week 64 from Period 2 Baseline (n=113)	1.46 (± 1.07)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Score: Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Score: Last Observation Carried Forward (LOCF): Period 3

End point description:

ASDAS: score combining assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP/ESR assessed on VAS ranging 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L & ESR measured in mm/hr. ASDAS ranged as inactive disease: 0<= ASDAS-CRP <1.3; moderate disease activity: 1.3<= ASDAS-CRP <2.1; high disease activity: 2.1<= ASDAS-CRP <=3.5; very high disease activity: 3.5< ASDAS-CRP. ASDAS-CRP is calculated as: 0.121*total back pain+0.110*subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln(CRP+1), Ln represents the natural logarithm. Full analysis set for Period 3 included all subjects who took study retreatment medication and
had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Period 3: Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=85)	2.97 (± 0.91)			
Change at Week 64 from Period 1 baseline (n=15)	-0.44 (± 1.45)			
Change at Week 64 from Period 2 baseline (n=15)	2.08 (± 0.80)			
Change at Week 64 from Period 3 baseline (n=14)	0.23 (± 0.68)			
Change at Week 68 from Period 1 baseline (n=85)	-1.92 (± 1.06)			
Change at Week 68 from Period 2 baseline (n=85)	0.67 (± 0.72)			
Change at Week 68 from Period 3 baseline (n=83)	-1.41 (± 0.98)			
Change at Week 72 from Period 1 baseline (n=87)	-2.09 (± 1.02)			
Change at Week 72 from Period 2 baseline (n=87)	0.50 (± 0.69)			

Change at Week 72 from Period 3 baseline (n=85)	-1.58 (± 0.99)			
Change at Week 76 from Period 1 baseline (n=87)	-2.12 (± 1.06)			
Change at Week 76 from Period 2 baseline (n=87)	0.47 (± 0.68)			
Change at Week 76 from Period 3 baseline (n=85)	-1.61 (± 1.04)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Score: Observed Cases (OC): Period 1

End point title	Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Score: Observed Cases (OC): Period 1

End point description:

ASDAS: score combining assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP/ESR assessed on VAS ranging 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L & ESR measured in mm/hr. ASDAS ranged as inactive disease: 0<= ASDAS-CRP <1.3; moderate disease activity: 1.3<= ASDAS-CRP <2.1; high disease activity: 2.1<= ASDAS-CRP <=3.5; very high disease activity: 3.5< ASDAS-CRP. ASDAS-CRP is calculated as: 0.121*total back pain+0.110*subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln(CRP+1), Ln represents the natural logarithm. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=209)	3.54 (± 0.87)			
Change at week 4 (n=208)	-1.27 (± 1.02)			
Change at week 8 (n=201)	-1.54 (± 1.10)			
Change at week 12 (n=197)	-1.66 (± 1.15)			
Change at week 16 (n=191)	-1.85 (± 1.12)			
Change at week 24 (n=190)	-2.13 (± 1.09)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Score: Observed Cases (OC): Period 2

End point title	Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Score: Observed Cases (OC): Period 2

End point description:

ASDAS: score combining assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP/ESR assessed on VAS ranging 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L & ESR measured in mm/hr. ASDAS ranged as inactive disease: 0<= ASDAS-CRP <1.3; moderate disease activity: 1.3<= ASDAS-CRP <2.1; high disease activity: 2.1<= ASDAS-CRP <=3.5; very high disease activity: 3.5< ASDAS-CRP. ASDAS-CRP is calculated as: 0.121*total back pain+0.110*subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln(CRP+1), Ln represents the natural logarithm. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1: Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.90 (± 0.20)			
Change at Week 28 from Period 1 Baseline (n=110)	-1.83 (± 1.14)			
Change at Week 28 from Period 2 Baseline (n=110)	0.66 (± 0.89)			
Change at Week 32 from Period 1 Baseline (n=93)	-1.76 (± 1.09)			
Change at Week 32 from Period 2 Baseline (n=93)	0.77 (± 0.93)			
Change at Week 40 from Period 1 Baseline (n=66)	-1.65 (± 1.09)			
Change at Week 40 from Period 2 Baseline (n=66)	0.74 (± 0.90)			
Change at Week 48 from Period 1 Baseline (n=50)	-1.59 (± 1.05)			
Change at Week 48 from Period 2 Baseline (n=50)	0.78 (± 0.91)			
Change at Week 56 from Period 1 Baseline (n=41)	-1.68 (± 1.04)			
Change at Week 56 from Period 2 Baseline (n=41)	0.63 (± 0.83)			
Change at Week 64 from Period 1 Baseline (n=34)	-1.46 (± 1.08)			
Change at Week 64 from Period 2 Baseline (n=34)	0.74 (± 1.02)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Score: Observed Cases (OC): Period 3

End point title	Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Score: Observed Cases (OC): Period 3

End point description:

ASDAS: score combining assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP/ESR assessed on VAS ranging 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L & ESR measured in mm/hr. ASDAS ranged as inactive disease: 0<= ASDAS-CRP <1.3; moderate disease activity: 1.3<= ASDAS-CRP <2.1; high disease activity: 2.1<= ASDAS-CRP <=3.5; very high disease activity: 3.5< ASDAS-CRP. ASDAS-CRP is calculated as: 0.121*total back pain+0.110*subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln(CRP+1), Ln represents the natural logarithm. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Period 3: Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=85)	2.97 (± 0.91)			
Change at Week 64 from Period 1 baseline (n=15)	-0.44 (± 1.45)			
Change at Week 64 from Period 2 baseline(n=15)	2.08 (± 0.80)			
Change at Week 64 from Period 3 baseline (n=14)	0.23 (± 0.68)			
Change at Week 68 from Period 1 baseline (n=84)	-1.94 (± 1.05)			
Change at Week 68 from Period 2 baseline (n=84)	0.65 (± 0.69)			
Change at Week 68 from Period 3 baseline (n=82)	-1.43 (± 0.97)			
Change at Week 72 from Period 1 baseline (n=86)	-2.11 (± 1.00)			
Change at Week 72 from Period 2 baseline (n=86)	0.47 (± 0.65)			

Change at Week 72 from Period 3 baseline (n=84)	-1.61 (± 0.97)			
Change at Week 76 from Period 1 baseline (n=85)	-2.17 (± 1.03)			
Change at Week 76 from Period 2 baseline (n=85)	0.45 (± 0.64)			
Change at Week 76 from Period 3 baseline (n=83)	-1.65 (± 1.02)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) Erythrocyte Sedimentation Rate (ESR) Score: Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) Erythrocyte Sedimentation Rate (ESR) Score: Last Observation Carried Forward (LOCF): Period 1

End point description:

ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0 = no disease activity and 100= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. ASDAS-ESR was calculated with the following equation: 0.8*total back pain+0.11*subject global+0.09*peripheral pain/swelling+0.07*duration of morning stiffness+ 0.29*ESR^1/2. ASDAS ranged as inactive disease: 0 <= ASDAS-ESR <1.3; active disease: 1.3 <= ASDAS-ESR =<2.1. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=209)	3.59 (± 0.90)			
Change at week 4 (n=204)	-1.27 (± 0.98)			
Change at week 8 (n=208)	-1.56 (± 1.08)			
Change at week 12(n=208)	-1.70 (± 1.15)			
Change at week 16 (n=208)	-1.81 (± 1.12)			
Change at week 24 (n=208)	-2.05 (± 1.17)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS)-Erythrocyte Sedimentation Rate (ESR) Score: Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS)-Erythrocyte Sedimentation Rate (ESR) Score: Last Observation Carried Forward (LOCF): Period 2

End point description:

ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0 = no disease activity and 100= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. ASDAS-ESR was calculated with the following equation: 0.8*total back pain+0.11*subject global+0.09*peripheral pain/swelling+0.07*duration of morning stiffness+ 0.29*ESR^1/2. ASDAS ranged as inactive disease: 0 <= ASDAS-ESR <1.3; active disease: 1.3 <= ASDAS-ESR =<2.1. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.92 (± 0.37)			
Change at Week 28 from Period 1 Baseline (n=112)	-1.81 (± 1.17)			
Change at Week 28 from Period 2 Baseline (n=112)	0.68 (± 0.90)			
Change at Week 32 from Period 1 Baseline (n=115)	-1.58 (± 1.22)			
Change at Week 32 from Period 2 Baseline (n=115)	0.93 (± 1.03)			
Change at Week 40 from Period 1 Baseline (n=115)	-1.34 (± 1.23)			
Change at Week 40 from Period 2 Baseline (n=115)	1.17 (± 1.05)			
Change at Week 48 from Period 1 Baseline (n=115)	-1.16 (± 1.22)			
Change at Week 48 from Period 2 Baseline (n=115)	1.34 (± 1.05)			
Change at Week 56 from Period 1 Baseline (n=115)	-1.11 (± 1.22)			
Change at Week 56 from Period 2 Baseline (n=115)	1.40 (± 1.07)			
Change at Week 64 from Period 1 Baseline (n=115)	-0.98 (± 1.21)			
Change at Week 64 from Period 2 Baseline (n=115)	1.52 (± 1.12)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS)-Erythrocyte Sedimentation Rate (ESR) Score: Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS)-Erythrocyte Sedimentation Rate (ESR) Score: Last Observation Carried Forward (LOCF): Period 3

End point description:

ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0 = no disease activity and 100= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. ASDAS-ESR was calculated with the following equation: 0.8*total back pain+0.11*subject global+0.09*peripheral pain/swelling+0.07*duration of morning stiffness+ 0.29*ESR^1/2. ASDAS ranged as inactive disease: 0 <= ASDAS-ESR <1.3; active disease: 1.3 <= ASDAS-ESR =<2.1. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Period 3: Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=87)	3.15 (± 0.72)			
Change at Week 64 from Period 1 Baseline (n=14)	-0.54 (± 1.50)			
Change at Week 64 from Period 2 Baseline(n=14)	2.05 (± 0.84)			
Change at Week 64 from Period 3 Baseline (n=14)	0.10 (± 0.71)			
Change at Week 68 from Period 1 Baseline (n=86)	-1.97 (± 1.01)			
Change at Week 68 from Period 2 Baseline (n=86)	0.65 (± 0.77)			
Change at Week 68 from Period 3 Baseline (n=86)	-1.60 (± 0.85)			
Change at Week 72 from Period 1 Baseline (n=87)	-2.15 (± 1.05)			
Change at Week 72 from Period 2 Baseline(n=87)	0.46 (± 0.74)			

Change at Week 72 from Period 3 Baseline (n=87)	-1.77 (± 0.87)			
Change at Week 76 from Period 1 Baseline (n=87)	-2.21 (± 1.09)			
Change at Week 76 from Period 2 Baseline (n=87)	0.41 (± 0.64)			
Change at Week 76 from Period 3 Baseline (n=87)	-1.83 (± 0.90)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) Erythrocyte Sedimentation Rate (ESR) Score: Observed Cases (OC): Period 1

End point title	Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) Erythrocyte Sedimentation Rate (ESR) Score: Observed Cases (OC): Period 1

End point description:

ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0 = no disease activity and 100= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. ASDAS-ESR was calculated with the following equation: 0.8*total back pain+0.11*subject global+0.09*peripheral pain/swelling+0.07*duration of morning stiffness+ 0.29*ESR^1/2. ASDAS ranged as inactive disease: 0 <= ASDAS-ESR <1.3; active disease: 1.3 <= ASDAS-ESR =<2.1. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=209)	3.59 (± 0.90)			
Change at week 4 (n=204)	-1.27 (± 0.98)			
Change at week 8 (n=200)	-1.57 (± 1.09)			
Change at week 12 (n=195)	-1.75 (± 1.16)			
Change at week 16 (n=190)	-1.89 (± 1.11)			
Change at week 24 (n=190)	-2.16 (± 1.12)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS)-Erythrocyte Sedimentation Rate (ESR) Score: Observed Cases (OC): Period 2

End point title	Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS)-Erythrocyte Sedimentation Rate (ESR) Score: Observed Cases (OC): Period 2

End point description:

ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0 = no disease activity and 100= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. ASDAS-ESR was calculated with the following equation: 0.8*total back pain+0.11*subject global+0.09*peripheral pain/swelling+0.07*duration of morning stiffness+ 0.29*ESR^1/2. ASDAS ranged as inactive disease: 0 <= ASDAS-ESR <1.3; active disease: 1.3 <= ASDAS-ESR =<2.1. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.92 (± 0.37)			
Change at Week 28 from Period 1 Baseline (n=112)	-1.81 (± 1.17)			
Change at Week 28 from Period 2 Baseline (n=112)	0.68 (± 0.90)			
Change at Week 32 from Period 1 Baseline (n=94)	-1.81 (± 1.12)			
Change at Week 32 from Period 2 Baseline (n=94)	0.70 (± 0.90)			
Change at Week 40 from Period 1 Baseline (n=69)	-1.59 (± 1.13)			
Change at Week 40 from Period 2 Baseline (n=69)	0.77 (± 0.91)			
Change at Week 48 from Period 1 Baseline (n=53)	-1.58 (± 1.11)			
Change at Week 48 from Period 2 Baseline (n=53)	0.81 (± 1.01)			
Change at Week 56 from Period 1 Baseline (n=41)	-1.71 (± 1.04)			
Change at Week 56 from Period 2 Baseline (n=41)	0.56 (± 0.83)			
Change at Week 64 from Period 1 Baseline (n=34)	-1.52 (± 1.16)			
Change at Week 64 from Period 2 Baseline (n=34)	0.73 (± 1.23)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS)-Erythrocyte Sedimentation Rate (ESR) Score: Observed Cases (OC): Period 3

End point title	Change From Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS)-Erythrocyte Sedimentation Rate (ESR) Score: Observed Cases (OC): Period 3

End point description:

ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0 = no disease activity and 100= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. ASDAS-ESR was calculated with the following equation: 0.8*total back pain+0.11*subject global+0.09*peripheral pain/swelling+0.07*duration of morning stiffness+ 0.29*ESR^1/2. ASDAS ranged as inactive disease: 0 <= ASDAS-ESR <1.3; active disease: 1.3 <= ASDAS-ESR =<2.1. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Period 3: Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=87)	3.15 (± 0.72)			
Change at Week 64 from Period 1 Baseline (n=14)	-0.54 (± 1.50)			
Change at Week 64 from Period 2 Baseline (n=14)	2.05 (± 0.84)			
Change at Week 64 from Period 3 Baseline (n=14)	0.10 (± 0.71)			
Change at Week 68 from Period 1 Baseline (n=85)	-1.99 (± 1.01)			
Change at Week 68 from Period 2 Baseline(n=85)	0.63 (± 0.74)			
Change at Week 68 from Period 3 Baseline(n=85)	-1.62 (± 0.83)			
Change at Week 72 from Period 1 Baseline (n=86)	-2.17 (± 1.04)			
Change at Week 72 from Period 2 Baseline (n=86)	0.43 (± 0.69)			
Change at Week 72 from Period 3 Baseline (n=86)	-1.80 (± 0.84)			
Change at Week 76 from Period 1 Baseline (n=84)	-2.22 (± 1.07)			
Change at Week 76 from Period 2 Baseline (n=84)	0.39 (± 0.59)			
Change at Week 76 from Period 3 Baseline (n=84)	-1.85 (± 0.88)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Major Improvement: Last Observation Carried Forward (LOCF): Period 1

End point title	Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Major Improvement: Last Observation Carried Forward (LOCF): Period 1

End point description:

Major improvement in ASDAS-CRP was defined as decrease from baseline >= 2.0 units. ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. The ASDAS-CRP is calculated with the following equation: 0.121*total back pain+0.110*subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln(CRP+1), Ln represents the natural logarithm. FAS for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF.

End point type	Secondary

End point timeframe:

Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	208			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 4	26.0 (20.36 to 32.22)			
Week 8	32.2 (26.14 to 38.77)			
Week 12	36.1 (29.76 to 42.74)			
Week 16	39.9 (33.43 to 46.66)			
Week 24	49.0 (42.30 to 55.81)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Major Improvement: Last Observation Carried Forward (LOCF): Period 2

End point title	Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Major Improvement: Last Observation Carried Forward (LOCF): Period 2

End point description:

Major improvement in ASDAS-CRP was defined as decrease from baseline >= 2.0 units. ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. The ASDAS-CRP is calculated with the following equation: 0.121*total back pain+0.110*subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln(CRP+1), Ln represents the natural logarithm. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 28 (n=110)	43.6 (34.63 to 52.97)			
Week 32 (n=113)	34.5 (26.23 to 43.58)			
Week 40 (n=113)	30.1 (22.22 to 38.97)			
Week 48 (n=113)	25.7 (18.30 to 34.26)			
Week 56 (n=113)	22.1 (15.24 to 30.42)			
Week 64 (n=113)	18.6 (12.25 to 26.50)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Major Improvement: Last Observation Carried Forward (LOCF): Period 3

End point title	Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Major Improvement: Last Observation Carried Forward (LOCF): Period 3

End point description:

Major improvement in ASDAS-CRP was defined as decrease from baseline >= 2.0 units. ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness,

subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. The ASDAS-CRP is calculated with the following equation: 0.121*total back pain+0.110*subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln(CRP+1), Ln represents the natural logarithm. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	6.7 (0.73 to 27.18)			
Week 68 (n=85)	41.2 (31.15 to 51.79)			
Week 72 (n=87)	55.2 (44.70 to 65.31)			
Week 76 (n=87)	54.0 (43.56 to 64.22)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Major Improvement: Observed Cases (OC): Period 1

End point title	Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Major Improvement: Observed Cases (OC): Period 1

End point description:

Major improvement in ASDAS-CRP was defined as decrease from baseline >= 2.0 units. ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. The ASDAS-CRP is calculated with the following equation: 0.121*total back pain+0.110*subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln(CRP+1), Ln represents the natural logarithm. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 4 (n=208)	26.0 (20.36 to 32.22)			
Week 8 (n=201)	32.8 (26.62 to 39.54)			
Week 12 (n=197)	38.1 (31.50 to 44.99)			
Week 16 (n=191)	42.4 (35.56 to 49.49)			
Week 24 (n=190)	52.6 (45.54 to 59.65)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Major Improvement: Observed Cases (OC): Period 2

End point title	Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Major Improvement: Observed Cases (OC): Period 2

End point description:

Major improvement in ASDAS-CRP was defined as decrease from baseline >= 2.0 units. ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. The ASDAS-CRP is calculated with the following equation: 0.121*total back pain+0.110*subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln(CRP+1), Ln represents the natural logarithm. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 28 (n=110)	43.6 (34.63 to 52.97)			
Week 32 (n=93)	39.8 (30.27 to 49.92)			
Week 40 (n=66)	37.9 (26.90 to 49.90)			

Week 48 (n=50)	34.0 (22.06 to 47.74)			
Week 56 (n=41)	31.7 (19.08 to 46.82)			
Week 64 (n=34)	23.5 (11.80 to 39.55)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Major Improvement: Observed Cases (OC): Period 3

End point title	Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Major Improvement: Observed Cases (OC): Period 3

End point description:

ASDAS-CRP clinically important improvement was defined as a decrease from baseline of >=1.1 units. ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. The ASDAS-CRP is calculated with the following equation: 0.121*total back pain+0.110* subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln (CRP+1), Ln represents the natural logarithm. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at

End point type	Secondary

End point timeframe:

Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	6.7 (0.73 to 27.18)			
Week 68 (n=84)	41.7 (31.55 to 52.34)			
Week 72 (n=86)	55.8 (45.27 to 65.97)			
Week 76 (n=85)	55.3 (44.70 to 65.54)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Clinically Important Improvement: Last Observation Carried Forward (LOCF): Period 1

End point title	Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Clinically Important Improvement: Last Observation Carried Forward (LOCF): Period 1

End point description:

ASDAS-CRP clinically important improvement was defined as a decrease from baseline of >=1.1 units. ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. The ASDAS-CRP is calculated with the following equation: 0.121*total back pain+0.110* subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln (CRP+1), Ln represents the natural logarithm. FAS for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF.

End point type	Secondary

End point timeframe:

Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	208			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 4	55.8 (48.98 to 62.40)			
Week 8	64.4 (57.75 to 70.69)			
Week 12	63.9 (57.26 to 70.24)			
Week 16	71.6 (65.24 to 77.43)			
Week 24	77.4 (71.37 to 82.68)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Clinically Important Improvement: Last Observation Carried Forward (LOCF): Period 2

End point title	Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Clinically Important Improvement: Last Observation Carried Forward (LOCF): Period 2

End point description:

ASDAS-CRP clinically important improvement was defined as a decrease from baseline of >=1.1 units. ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease

activity. CRP measured in mg/L and ESR measured in mm/hr. The ASDAS-CRP is calculated with the following equation: 0.121*total back pain+0.110* subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln (CRP+1), Ln represents the natural logarithm. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific

End point type	Secondary

End point timeframe:

Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 28 (n=110)	74.5 (65.84 to 81.98)			
Week 32 (n=113)	70.8 (61.97 to 78.58)			
Week 40(n=113)	59.3 (50.09 to 68.02)			
Week 48 (n=113)	55.8 (46.55 to 64.67)			
Week 56 (n=113)	54.9 (45.67 to 63.82)			
Week 64 (n=113)	50.4 (41.31 to 59.55)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Clinically Important Improvement: Last Observation Carried Forward (LOCF): Period 3

End point title	Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Clinically Important Improvement: Last Observation Carried Forward (LOCF): Period 3

End point description:

ASDAS-CRP clinically important improvement was defined as a decrease from baseline of >=1.1 units. ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. The ASDAS-CRP is calculated with the following equation: 0.121*total back pain+0.110* subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln (CRP+1), Ln represents the natural logarithm. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	26.7 (9.74 to 51.66)			
Week 68 (n=84)	80.0 (70.58 to 87.42)			
Week 72 (n=86)	82.8 (73.82 to 89.56)			
Week 76 (n=85)	79.3 (69.93 to 86.78)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Clinically Important Improvement: Observed Cases (OC): Period 1

End point title	Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Clinically Important Improvement: Observed Cases (OC): Period 1

End point description:

ASDAS-CRP clinically important improvement was defined as a decrease from baseline of >=1.1 units. ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. The ASDAS-CRP is calculated with the following equation: 0.121*total back pain+0.110* subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln (CRP+1), Ln represents the natural logarithm. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 4 (n=208)	55.8 (48.98 to 62.40)			

Week 8 (n=201)	64.7 (57.90 to 71.04)			
Week 12 (n=197)	65.5 (58.66 to 71.86)			
Week 16 (n=191)	74.3 (67.82 to 80.14)			
Week 24 (n=190)	81.1 (75.04 to 86.13)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Clinically Important Improvement: Observed Cases (OC): Period 2

End point title	Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Clinically Important Improvement: Observed Cases (OC): Period 2

End point description:

ASDAS-CRP clinically important improvement was defined as a decrease from baseline of >=1.1 units. ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. The ASDAS-CRP is calculated with the following equation: 0.121*total back pain+0.110* subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln (CRP+1), Ln represents the natural logarithm. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 28 (n=110)	74.5 (65.84 to 81.98)			
Week 32 (n=93)	79.6 (70.55 to 86.79)			
Week 40 (n=66)	68.2 (56.35 to 78.46)			
Week 48 (n=50)	72.0 (58.58 to 82.96)			
Week 56 (n=41)	78.0 (63.75 to 88.55)			
Week 64 (n=34)	70.6 (54.07 to 83.77)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Clinically Important Improvement: Observed Cases (OC): Period 3

End point title	Percentage of Subjects Who Achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) C-Reactive Protein (CRP) Clinically Important Improvement: Observed Cases (OC): Period 3

End point description:

ASDAS-CRP clinically important improvement was defined as a decrease from baseline of >=1.1 units. ASDAS is a score combining the assessment of back pain, peripheral pain/swelling, duration of morning stiffness, subject global assessment of disease activity and CRP or ESR. All parameters other than CRP or ESR assessed on a VAS ranging from 0-10 cm, where 0= no disease activity and 10= high disease activity. CRP measured in mg/L and ESR measured in mm/hr. The ASDAS-CRP is calculated with the following equation: 0.121*total back pain+0.110* subject global+0.073*peripheral pain/swelling+0.058*duration of morning stiffness+0.579*Ln (CRP+1), Ln represents the natural

End point type	Secondary

End point timeframe:

Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	26.7 (9.74 to 51.66)			
Week 68 (n=84)	81.0 (71.59 to 88.23)			
Week 72 (n=86)	83.7 (74.87 to 90.35)			
Week 76 (n=85)	81.2 (71.90 to 88.37)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Nocturnal Back Pain: Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in Nocturnal Back Pain: Last Observation

	Carried Forward (LOCF): Period 1

End point description:

Subjects assessed their nocturnal back pain over the last 48 hours on a 100 mm VAS scale ranged from 0 mm (none) to 100 mm (severe), where higher scores indicated more pain. The reported values were converted to centimeter (cm) for analysis. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: cm				
arithmetic mean (standard deviation)				
Baseline (n=209)	5.92 (± 2.52)			
Change at week 4 (n=208)	-2.53 (± 2.55)			
Change at week 8(n=208)	-3.10 (± 2.76)			
Change at week 12 (n=208)	-3.25 (± 2.76)			
Change at week 16 (n=208)	-3.55 (± 2.67)			
Change at week 24 (n=208)	-4.14 (± 2.88)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Nocturnal Back Pain: Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in Nocturnal Back Pain: Last Observation Carried Forward (LOCF): Period 2

End point description:

Subjects assessed their nocturnal back pain over the last 48 hours on a 100 mm VAS scale ranged from 0 mm (none) to 100 mm (severe), where higher scores indicated more pain. The reported values were converted to centimeter (cm) for analysis. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: cm				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.63 (± 1.07)			
Change at Week 28 from Period 1 Baseline (n=111)	-3.77 (± 3.20)			
Change at Week 28 from Period 2 Baseline (n=111)	1.08 (± 2.33)			
Change at Week 32 from Period 1 Baseline (n=114)	-3.05 (± 3.07)			
Change at Week 32 from Period 2 Baseline (n=114)	1.80 (± 2.65)			
Change at Week 40 from Period 1 Baseline (n=114)	-2.64 (± 3.13)			
Change at Week 40 from Period 2 Baseline (n=114)	2.22 (± 2.89)			
Change at Week 48 from Period 1 Baseline (n=114)	-2.32 (± 3.26)			
Change at Week 48 from Period 2 Baseline (n=114)	2.53 (± 2.93)			
Change at Week 56 from Period 1 Baseline	-2.11 (± 3.14)			
Change at Week 56 from Period 2 Baseline (n=114)	2.74 (± 3.00)			
Change at Week 64 from Period 1 Baseline (n=114)	-1.77 (± 3.14)			
Change at Week 64 from Period 2 Baseline (n=114)	3.08 (± 3.06)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Nocturnal Back Pain: Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in Nocturnal Back Pain: Last Observation Carried Forward (LOCF): Period 3

End point description:

Subjects assessed their nocturnal back pain over the last 48 hours on a 100 mm VAS scale ranged from 0 mm (none) to 100 mm (severe), where higher scores indicated more pain. The reported values were converted to centimeter (cm) for analysis. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Period 3: Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: cm				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=86)	5.54 (± 2.63)			
Change at Week 64 from Period 1 Baseline (n=15)	-0.28 (± 4.01)			
Change at Week 64 from Period 2 Baseline (n=15)	4.35 (± 2.87)			
Change at Week 64 from Period 3 Baseline (n=15)	1.29 (± 3.36)			
Change at Week 68 from Period 1 Baseline (n=86)	-4.03 (± 2.81)			
Change at Week 68 from Period 2 Baseline(n=86)	1.33 (± 1.92)			
Change at Week 68 from Period 3 Baseline(n=86)	-3.59 (± 2.64)			
Change at Week 72 from Period 1 Baseline(n=87)	-4.43 (± 2.70)			
Change at Week 72 from Period 2 Baseline (n=87)	0.94 (± 1.87)			
Change at Week 72 from Period 3 Baseline(n=86)	-3.96 (± 2.64)			
Change at Week 76 from Period 1 Baseline(n=87)	-4.72 (± 2.82)			
Change at Week 76 from Period 2 Baseline(n=87)	0.64 (± 1.51)			
Change at Week 76 from Period 3 Baseline(n=87)	-4.25 (± 2.74)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Nocturnal Back Pain: Observed Cases (OC): Period 1

End point title	Change From Baseline in Nocturnal Back Pain: Observed Cases (OC): Period 1

End point description:

Subjects assessed their nocturnal back pain over the last 48 hours on a 100 mm VAS scale ranged from 0 mm (none) to 100 mm (severe), where higher scores indicated more pain. The reported values were converted to centimeter (cm) for analysis. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: cm				
arithmetic mean (standard deviation)				
Baseline (n=209)	5.92 (± 2.52)			
Change at week 4 (n=208)	-2.53 (± 2.55)			
Change at week 8 (n=201)	-3.10 (± 2.79)			
Change at week 12 (n=198)	-3.32 (± 2.78)			
Change at week 16 (n=192)	-3.68 (± 2.68)			
Change at week 24 (n=190)	-4.32 (± 2.87)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Nocturnal Back Pain: Observed Cases (OC): Period 2

End point title	Change From Baseline in Nocturnal Back Pain: Observed Cases (OC): Period 2

End point description:

Subjects assessed their nocturnal back pain over the last 48 hours on a 100 mm VAS scale ranged from 0 mm (none) to 100 mm (severe), where higher scores indicated more pain. The reported values were converted to centimeter (cm) for analysis. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: cm				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.63 (± 1.07)			
Change at Week 28 from Period 1 Baseline (n=111)	-3.77 (± 3.20)			
Change at Week 28 from Period 2 Baseline (n=111)	1.08 (± 2.33)			
Change at Week 32 from Period 1 Baseline (n=93)	-3.50 (± 2.61)			
Change at Week 32 from Period 2 Baseline (n=93)	1.33 (± 2.38)			
Change at Week 40 from Period 1 Baseline (n=68)	-3.12 (± 2.79)			
Change at Week 40 from Period 2 Baseline (n=68)	1.46 (± 2.67)			
Change at Week 48 from Period 1 Baseline (n=53)	-3.03 (± 3.02)			

Change at Week 48 from Period 2 Baseline (n=53)	1.52 (± 2.73)			
Change at Week 56 from Period 1 Baseline (n=42)	-3.22 (± 2.53)			
Change at Week 56 from Period 2 Baseline(n=42)	1.24 (± 2.69)			
Change at Week 64 from Period 1 Baseline (n=34)	-2.28 (± 2.77)			
Change at Week 64 from Period 2 Baseline (n=34)	1.53 (± 3.01)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Nocturnal Back Pain: Observed Cases (OC): Period 3

End point title	Change From Baseline in Nocturnal Back Pain: Observed Cases (OC): Period 3

End point description:

Subjects assessed their nocturnal back pain over the last 48 hours on a 100 mm VAS scale ranged from 0 mm (none) to 100 mm (severe), where higher scores indicated more pain. The reported values were converted to centimeter (cm) for analysis. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Period 3: Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: cm				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=86)	5.54 (± 2.63)			
Change at Week 64 from Period 1 Baseline (n=15)	-0.28 (± 4.01)			
Change at Week 64 from Period 2 Baseline(n=15)	4.35 (± 2.87)			
Change at Week 64 from Period 3 Baseline (n=14)	1.29 (± 3.36)			
Change at Week 68 from Period 1 Baseline (n=85)	-4.07 (± 2.81)			
Change at Week 68 from Period 2 Baseline (n=85)	1.34 (± 1.93)			
Change at Week 68 from Period 3 Baseline (n=84)	-3.62 (± 2.64)			
Change at Week 72 from Period 1 Baseline (n=87)	-4.43 (± 2.70)			
Change at Week 72 from Period 2 Baseline (n=87)	0.94 (± 1.87)			

Change at Week 72 from Period 3 Baseline (n=86)	-3.96 (± 2.64)			
Change at Week 76 from Period 1 Baseline (n=85)	-4.84 (± 2.75)			
Change at Week 76 from Period 2 Baseline (n=85)	0.64 (± 1.51)			
Change at Week 76 from Period 3 Baseline (n=84)	-4.36 (± 2.68)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total Back Pain: Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in Total Back Pain: Last Observation Carried Forward (LOCF): Period 1

End point description:

Subjects assessed their total back pain over the last 48 hours on a 100 mm VAS scale ranged from 0 mm (none) to 100 mm (severe), where higher scores indicated more pain. The reported values were converted to cm for analysis. Full analysis set for Period 1 included all sub who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: cm				
arithmetic mean (standard deviation)				
Baseline (n=209)	5.98 (± 2.41)			
Change at week 4 (n=208)	-2.39 (± 2.36)			
Change at week 8 (n=208)	-2.96 (± 2.54)			
Change at week 12 (n=208)	-3.15 (± 2.60)			
Change at week 16 (n=208)	-3.44 (± 2.54)			
Change at week 24 (n=208)	-4.05 (± 2.79)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total Back Pain: Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in Total Back Pain: Last Observation Carried Forward (LOCF): Period 2

End point description:

Subjects assessed their total back pain over the last 48 hours on a 100 mm VAS scale ranged from 0 mm (none) to 100 mm (severe), where higher scores indicated more pain. The reported values were converted to cm for analysis. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: cm				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.71 (± 1.09)			
Change at Week 28 from Period 1 Baseline (n=111)	-3.68 (± 3.04)			
Change at Week 28 from Period 2 Baseline (n=111)	1.09 (± 2.20)			
Change at Week 32 from Period 1 Baseline (n=114)	-2.92 (± 3.06)			
Change at Week 32 from Period 2 Baseline(n=114)	1.84 (± 2.58)			
Change at Week 40 from Period 1 Baseline (n=114)	-2.48 (± 3.17)			
Change at Week 40 from Period 2 Baseline (n=114)	2.28 (± 2.87)			
Change at Week 48 from Period 1 Baseline (n=114)	-2.12 (± 3.19)			
Change at Week 48 from Period 2 Baseline (n=114)	2.64 (± 2.90)			
Change at Week 56 from Period 1 Baseline (n=114)	-1.95 (± 3.16)			
Change at Week 56 from Period 2 Baseline (n=114)	2.81 (± 2.96)			
Change at Week 64 from Period 1 Baseline (n=114)	-1.66 (± 3.13)			
Change at Week 64 from Period 2 Baseline (n=114)	3.10 (± 3.02)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total Back Pain: Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in Total Back Pain: Last Observation Carried Forward (LOCF): Period 3

End point description:

Subjects assessed their total back pain over the last 48 hours on a 100 mm VAS scale ranged from 0

mm (none) to 100 mm (severe), where higher scores indicated more pain. The reported values were converted to cm for analysis. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Period 3: Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: cm				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=86)	5.66 (± 2.55)			
Change at Week 64 from Period 1 Baseline (n=15)	-0.10 (± 4.08)			
Change at Week 64 from Period 2 Baseline (n=15)	4.34 (± 2.70)			
Change at Week 64 from Period 3 Baseline (n=14)	1.07 (± 2.88)			
Change at Week 68 from Period 1 Baseline (n=86)	-3.73 (± 2.66)			
Change at Week 68 from Period 2 Baseline (n=86)	1.35 (± 1.96)			
Change at Week 68 from Period 3 Baseline (n=85)	-3.60 (± 2.55)			
Change at Week 72 from Period 1 Baseline (n=87)	-4.21 (± 2.42)			
Change at Week 72 from Period 2 Baseline (n=87)	0.89 (± 1.81)			
Change at Week 72 from Period 3 Baseline (n=86)	-4.03 (± 2.50)			
Change at Week 76 from Period 1 Baseline (n=87)	-4.32 (± 2.70)			
Change at Week 76 from Period 2 Baseline (n=87)	0.77 (± 1.52)			
Change at Week 76 from Period 3 Baseline (n=86)	-4.15 (± 2.72)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total Back Pain: Observed Cases (OC): Period 1

End point title	Change From Baseline in Total Back Pain: Observed Cases (OC): Period 1

End point description:

Subjects assessed their total back pain over the last 48 hours on a 100 mm VAS scale ranged from 0 mm (none) to 100 mm (severe), where higher scores indicated more pain. The reported values were converted to cm for analysis. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: cm				
arithmetic mean (standard deviation)				
Baseline (n=209)	5.98 (± 2.41)			
Change at week 4 (n=208)	-2.39 (± 2.36)			
Change at week 8 (n-201)	-2.97 (± 2.56)			
Change at week 12 (n=198)	-3.23 (± 2.62)			
Change at week 16 (n=192)	-3.56 (± 2.53)			
Change at week 24 (n=190)	-4.24 (± 2.75)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total Back Pain: Observed Cases (OC): Period 2

End point title	Change From Baseline in Total Back Pain: Observed Cases (OC): Period 2

End point description:

Subjects assessed their total back pain over the last 48 hours on a 100 mm VAS scale ranged from 0 mm (none) to 100 mm (severe), where higher scores indicated more pain. The reported values were converted to cm for analysis. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: cm				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.71 (± 1.09)			
Change at Week 28 from Period 1 Baseline (n=111)	-3.68 (± 3.04)			
Change at Week 28 from Period 2 Baseline(n=111)	1.09 (± 2.20)			
Change at Week 32 from Period 1 Baseline (n=93)	-3.43 (± 2.67)			

Change at Week 32 from Period 2 Baseline(n=93)	1.38 (± 2.35)			
Change at Week 40 from Period 1 Baseline (n=68)	-2.97 (± 2.81)			
Change at Week 40 from Period 2 Baseline(n=68)	1.52 (± 2.69)			
Change at Week 48 from Period 1 Baseline(n=53)	-2.91 (± 2.78)			
Change at Week 48 from Period 2 Baseline (n=53)	1.54 (± 2.65)			
Change at Week 56 from Period 1 Baseline (n=42)	-3.15 (± 2.53)			
Change at Week 56 from Period 2 Baseline (n=42)	1.15 (± 2.52)			
Change at Week 64 from Period 1 Baseline (n=34)	-2.56 (± 2.73)			
Change at Week 64 from Period 2 Baseline(n=34)	1.39 (± 2.96)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total Back Pain: Observed Cases (OC): Period 3

End point title	Change From Baseline in Total Back Pain: Observed Cases (OC): Period 3

End point description:

Subjects assessed their total back pain over the last 48 hours on a 100 mm VAS scale ranged from 0 mm (none) to 100 mm (severe), where higher scores indicated more pain. The reported values were converted to cm for analysis. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Period 3: Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: cm				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=86)	5.66 (± 2.55)			
Change at Week 64 from Period 1 Baseline (n=15)	-0.10 (± 4.08)			
Change at Week 64 from Period 2 Baseline (n=15)	4.34 (± 2.70)			
Change at Week 64 from Period 3 Baseline (n=14)	1.07 (± 2.88)			
Change at Week 68 from Period 1 Baseline (n=85)	-3.76 (± 2.67)			

Change at Week 68 from Period 2 Baseline (n=85)	1.35 (± 1.97)			
Change at Week 68 from Period 3 Baseline (n=84)	-3.63 (± 2.54)			
Change at Week 72 from Period 1 Baseline	-4.21 (± 2.42)			
Change at Week 72 from Period 2 Baseline (n=87)	0.89 (± 1.81)			
Change at Week 72 from Period 3 Baseline (n=87)	-4.03 (± 2.50)			
Change at Week 76 from Period 1 Baseline (n=86)	-4.41 (± 2.67)			
Change at Week 76 from Period 2 Baseline (n=85)	0.78 (± 1.53)			
Change at Week 76 from Period 3 Baseline (n=84)	-4.24 (± 2.69)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI): Observed Cases (OC): Period 1

End point title	Mean Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI): Observed Cases (OC): Period 1

End point description:

BASFI is composed of 10 questions related to the subject’s ability to function. Each question scored by the subject on a 100 mm scale ranging from 0 (easy) to 100 (impossible), where higher scores indicated more difficulty in subject's ability to function. The BASFI total score calculated as mean of the scores for these 10 questions and converted to cm for analysis. BASFI total score was ranged from 0 (easy) to 10 (impossible), where higher scores indicated more difficulty in subject’s ability to function due to ankylosing spondylitis. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, “n” signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=209)	4.66 (± 2.21)			
Change at week 4 (n=208)	-1.62 (± 1.88)			
Change at week 8 (n=201)	-2.22 (± 2.21)			
Change at week 12 (n=198)	-2.44 (± 2.34)			
Change at week 16 (n=192)	-2.73 (± 2.27)			
Change at week 24 (n=190)	-3.24 (± 2.57)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI): Observed Cases (OC): Period 2

End point title	Mean Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI): Observed Cases (OC): Period 2

End point description:

BASFI is composed of 10 questions related to the subject's ability to function. Each question scored by the subject on a 100 mm scale ranging from 0 (easy) to 100 (impossible), where higher scores indicated more difficulty in subject's ability to function. The BASFI total score calculated as mean of the scores for these 10 questions and converted to cm for analysis. BASFI total score was ranged from 0 (easy) to 10 (impossible), where higher scores indicated more difficulty in subject's ability to function due to ankylosing spondylitis. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.59 (± 0.88)			
Change at Week 28 from Period 1 Baseline (n=111)	-3.00 (± 2.78)			
Change at Week 28 from Period 2 Baseline (n=111)	0.90 (± 1.97)			
Change at Week 32 from Period 1 Baseline (n=93)	-3.10 (± 2.52)			
Change at Week 32 from Period 2 Baseline (n=93)	0.88 (± 1.86)			
Change at Week 40 from Period 1 Baseline (n=68)	-2.88 (± 2.41)			
Change at Week 40 from Period 2 Baseline (n=68)	0.98 (± 1.63)			
Change at Week 48 from Period 1 Baseline (n=53)	-2.84 (± 2.37)			
Change at Week 48 from Period 2 Baseline (n=53)	0.98 (± 1.76)			
Change at Week 56 from Period 1 Baseline (n=41)	-2.97 (± 2.14)			
Change at Week 56 from Period 2 Baseline (n=41)	0.73 (± 1.57)			

Change at Week 64 from Period 1 Baseline (n=34)	-2.33 (± 2.08)			
Change at Week 64 from Period 2 Baseline (n=34)	1.21 (± 2.41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI): Observed Cases (OC): Period 3

End point title	Mean Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI): Observed Cases (OC): Period 3

End point description:

BASFI is composed of 10 questions related to the subject's ability to function. Each question scored by the subject on a 100 mm scale ranging from 0 (easy) to 100 (impossible), where higher scores indicated more difficulty in subject's ability to function. The BASFI total score calculated as mean of the scores for these 10 questions and converted to cm for analysis. BASFI total score was ranged from 0 (easy) to 10 (impossible), where higher scores indicated more difficulty in subject's ability to function due to ankylosing spondylitis. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1: Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Period 3: Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=86)	4.14 (± 2.44)			
Change at Week 64 from Period 1 Baseline (n=15)	-0.62 (± 3.52)			
Change at Week 64 from Period 2 Baseline (n=15)	3.11 (± 2.16)			
Change at Week 64 from Period 3 Baseline (n=15)	0.78 (± 2.73)			
Change at Week 68 from Period 1 Baseline (n=85)	-2.99 (± 2.30)			
Change at Week 68 from Period 2 Baseline (n=85)	1.13 (± 1.58)			
Change at Week 68 from Period 3 Baseline (n=84)	-2.41 (± 2.00)			
Change at Week 72 from Period 1 Baseline (n=87)	-3.25 (± 2.35)			
Change at Week 72 from Period 2 Baseline (n=87)	0.84 (± 1.40)			
Change at Week 72 from Period 3 Baseline (n=86)	-2.67 (± 2.22)			
Change at Week 76 from Period 1 Baseline (n=85)	-3.47 (± 2.49)			

Change at Week 76 from Period 2 Baseline (n=85)	0.67 (± 1.30)			
Change at Week 76 from Period 3 Baseline (n=84)	-2.89 (± 2.23)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI): Last Observation Carried Forward (LOCF): Period 1

End point title	Mean Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI): Last Observation Carried Forward (LOCF): Period 1

End point description:

BASFI is composed of 10 questions related to the subject's ability to function. Each question scored by the subject on a 100 mm scale ranging from 0 (easy) to 100 (impossible), where higher scores indicated more difficulty in subject's ability to function. The BASFI total score calculated as mean of the scores for these 10 questions and converted to cm for analysis. BASFI total score was ranged from 0 (easy) to 10 (impossible), where higher scores indicated more difficulty in subject's ability to function due to ankylosing spondylitis. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=209)	4.66 (± 2.21)			
Change at week 4 (n=208)	-1.62 (± 1.88)			
Change at week 8 (n=208)	-2.23 (± 2.19)			
Change at week 12 (n=208)	-2.39 (± 2.31)			
Change at week 16 (n=208)	-2.65 (± 2.24)			
Change at week 24 (n=208)	-3.10 (± 2.54)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI): Last Observation Carried Forward (LOCF): Period 2

End point title	Mean Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI): Last Observation Carried Forward (LOCF): Period 2

End point description:

BASFI is composed of 10 questions related to the subject's ability to function. Each question scored by the subject on a 100 mm scale ranging from 0 (easy) to 100 (impossible), where higher scores indicated more difficulty in subject's ability to function. The BASFI total score calculated as mean of the scores for these 10 questions and converted to cm for analysis. BASFI total score was ranged from 0 (easy) to 10 (impossible), where higher scores indicated more difficulty in subject's ability to function due to ankylosing spondylitis. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.59 (± 0.88)			
Change at Week 28 from Period 1 Baseline (n=111)	-3.00 (± 2.78)			
Change at Week 28 from Period 2 Baseline (n=111)	0.90 (± 1.97)			
Change at Week 32 from Period 1 Baseline (n=114)	-2.54 (± 2.88)			
Change at Week 32 from Period 2 Baseline (n=114)	1.35 (± 2.22)			
Change at Week 40 from Period 1 Baseline (n=114)	-2.21 (± 2.90)			
Change at Week 40 from Period 2 Baseline (n=114)	1.67 (± 2.29)			
Change at Week 48 from Period 1 Baseline (n=114)	-1.97 (± 2.89)			
Change at Week 48 from Period 2 Baseline (n=114)	1.92 (± 2.36)			
Change at Week 56 from Period 1 Baseline (n=114)	-1.85 (± 2.88)			
Change at Week 56 from Period 2 Baseline (n=114)	2.03 (± 2.40)			
Change at Week 64 from Period 1 Baseline (n=114)	-1.62 (± 2.84)			
Change at Week 64 from Period 2 Baseline (n=114)	2.27 (± 2.51)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI): Last Observation Carried Forward (LOCF): Period 3

End point title	Mean Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI): Last Observation Carried Forward

	(LOCF): Period 3

End point description:

BASFI is composed of 10 questions related to the subject's ability to function. Each question scored by the subject on a 100 mm scale ranging from 0 (easy) to 100 (impossible), where higher scores indicated more difficulty in subject's ability to function. The BASFI total score calculated as mean of the scores for these 10 questions and converted to cm for analysis. BASFI total score was ranged from 0 (easy) to 10 (impossible), where higher scores indicated more difficulty in subject's ability to function due to ankylosing spondylitis. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Period 3: Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=86)	4.14 (± 2.44)			
Change at Week 64 from Period 1 Baseline (n=15)	-0.62 (± 3.52)			
Change at Week 64 from Period 2 Baseline (n=15)	3.11 (± 2.16)			
Change at Week 64 from Period 3 Baseline (n=14)	0.78 (± 2.73)			
Change at Week 68 from Period 1 Baseline (n=86)	-2.98 (± 2.29)			
Change at Week 68 from Period 2 Baseline (n=86)	1.14 (± 1.57)			
Change at Week 68 from Period 3 Baseline (n=85)	-2.38 (± 2.01)			
Change at Week 72 from Period 1 Baseline (n=87)	-3.25 (± 2.35)			
Change at Week 72 from Period 2 Baseline (n=87)	0.84 (± 1.40)			
Change at Week 72 from Period 3 Baseline (n=86)	-2.67 (± 2.22)			
Change at Week 76 from Period 1 Baseline (n=87)	-3.41 (± 2.49)			
Change at Week 76 from Period 2 Baseline (n=87)	0.68 (± 1.29)			
Change at Week 76 from Period 3 Baseline (n=86)	-2.83 (± 2.24)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Total Score: Observed Cases (OC): Period 1

End point title	Mean Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Total Score: Observed Cases (OC): Period 1

End point description:

BASDAI consisted of 6 questions related to disease activity. Each of first 5 questions was scored by subject on a 100 mm scale ranging from 0 (none) to 100 (very severe), where higher scores indicated more severe disease activity. Sixth question, related to duration of morning stiffness measured on a scale for 0 (0 hours) to 100 (2 hours), where higher scores indicated larger duration of morning stiffness. BASDAI score was obtained by computing mean score for the 2 questions related to morning stiffness (questions 5 [severity of morning stiffness] and 6 [duration of morning stiffness]) and then adding that value to sum of the scores for first 4 questions and then dividing the total by 5. This can be written as BASDAI=(Q1+Q2+Q3+Q4+(Q5+Q6)/2)/5.BASDAI total score ranged from 0 to 10, where higher scores indicated more severe disease activity. Reported values were converted to cm for analysis. FAS for Period 1 was analyzed. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=209)	6.41 (± 1.80)			
Change at week 4 (n=208)	-2.39 (± 1.93)			
Change at week 8 (n=201)	-3.08 (± 2.17)			
Change at week 12 (n=198)	-3.40 (± 2.37)			
Change at week 16 (n=192)	-3.91 (± 2.31)			
Change at week 24 (n=190)	-4.65 (± 2.36)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Total Score: Observed Cases (OC): Period 2

End point title	Mean Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Total Score: Observed Cases (OC): Period 2

End point description:

BASDAI consisted of 6 questions related to disease activity. Each of first 5 questions was scored by subject on a 100 mm scale ranging from 0 (none) to 100 (very severe), where higher scores indicated more severe disease activity. Sixth question, related to duration of morning stiffness measured on a scale for 0 (0 hours) to 100 (2 hours), where higher scores indicated larger duration of morning stiffness. BASDAI score was obtained by computing mean score for the 2 questions related to morning stiffness (questions 5 [severity of morning stiffness] and 6 [duration of morning stiffness]) and then adding that value to sum of the scores for first 4 questions and then dividing the total by 5. This can be written as BASDAI=(Q1+Q2+Q3+Q4+(Q5+Q6)/2)/5.BASDAI total score ranged from 0 to 10, where higher scores indicated more severe disease activity. Reported values were converted to cm for analysis. FAS for Period 2 was analyzed. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.63 (± 0.66)			
Change at Week 28 from Period 1 Baseline (n=112)	-4.10 (± 2.61)			
Change at Week 28 from Period 2 Baseline(n=112)	1.38 (± 2.27)			
Change at Week 32 from Period 1 Baseline (n=94)	-4.11 (± 2.40)			
Change at Week 32 from Period 2 Baseline (n=94)	1.37 (± 2.17)			
Change at Week 40 from Period 1 Baseline (n=69)	-3.77 (± 2.46)			
Change at Week 40 from Period 2 Baseline (n=69)	1.60 (± 2.35)			
Change at Week 48 from Period 1 Baseline ((n=53)	-3.78 (± 2.32)			
Change at Week 48 from Period 2 Baseline (n=58)	1.65 (± 2.39)			
Change at Week 56 from Period 1 Baseline (n=42)	-3.97 (± 2.18)			
Change at Week 56 from Period 2 Baseline (n=42)	1.20 (± 1.83)			
Change at Week 64 from Period 1 Baseline (n=34)	-3.49 (± 2.47)			
Change at Week 64 from Period 2 Baseline (n=34)	1.49 (± 2.66)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Total Score: Observed Cases (OC): Period 3

End point title	Mean Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Total Score: Observed Cases (OC): Period 3

End point description:

BASDAI consisted of 6 questions related to disease activity. Each of first 5 questions was scored by subject on a 100 mm scale ranging from 0 (none) to 100 (very severe), where higher scores indicated more severe disease activity. Sixth question, related to duration of morning stiffness measured on a scale for 0 (0 hours) to 100 (2 hours), where higher scores indicated larger duration of morning stiffness. BASDAI score was obtained by computing mean score for the 2 questions related to morning stiffness (questions 5 [severity of morning stiffness] and 6 [duration of morning stiffness]) and then adding that value to sum of the scores for first 4 questions and then dividing the total by 5. This can be written as BASDAI=(Q1+Q2+Q3+Q4+(Q5+Q6)/2)/5.BASDAI total score ranged from 0 to 10, where

higher scores indicated more severe disease activity. Reported values were converted to cm for analysis. FAS for Period 3 was analyzed. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1: Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Period 3: Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=87)	5.53 (± 2.24)			
Change at Week 64 from Period 1 Baseline (n=15)	-0.92 (± 2.82)			
Change at Week 64 from Period 2 Baseline (n=15)	4.63 (± 2.14)			
Change at Week 64 from Period 3 Baseline (n=15)	0.37 (± 1.23)			
Change at Week 68 from Period 1 Baseline (n=85)	-4.04 (± 2.10)			
Change at Week 68 from Period 2 Baseline (n=85)	1.66 (± 1.87)			
Change at Week 68 from Period 3 Baseline(n=85)	-3.26 (± 2.15)			
Change at Week 72 from Period 1 Baseline (n=87)	-4.47 (± 2.11)			
Change at Week 72 from Period 2 Baseline(n=87)	1.22 (± 1.73)			
Change at Week 72 from Period 3 Baseline (n=87)	-3.65 (± 2.33)			
Change at Week 76 from Period 1 Baseline (n=85)	-4.87 (± 2.21)			
Change at Week 76 from Period 2 Baseline (n=85)	0.91 (± 1.51)			
Change at Week 76 from Period 3 Baseline (n=85)	-4.03 (± 2.38)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Total Score: Last Observation Carried Forward (LOCF): Period 1

End point title	Mean Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Total Score: Last Observation Carried Forward (LOCF): Period 1

End point description:

BASDAI: 6 questions related to disease activity. Each of first 5 questions was scored by subject on a 100 mm scale ranging from 0 (none) to 100 (very severe), where higher scores indicated more severe disease activity. Sixth question, related to duration of morning stiffness measured on a scale for 0 (0

hours) to 100 (2 hours), where higher scores indicated larger duration of morning stiffness. BASDAI score was obtained by computing mean score for the 2 questions related to morning stiffness (questions 5 [severity of morning stiffness] and 6 [duration of morning stiffness]) and then adding that value to sum of scores for first 4 questions and then dividing total by 5.
BASDAI=(Q1+Q2+Q3+Q4+(Q5+Q6)/2)/5.BASDAI total score ranged from 0 to 10, where higher scores indicated more severe disease activity. Reported values were converted to cm for analysis. FAS for Period 1 was analyzed. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=209)	6.41 (± 1.80)			
Change at week 4 (n=208)	-2.39 (± 1.93)			
Change at week 8 (n=208)	-3.07 (± 2.16)			
Change at week 12 (n=208)	-3.34 (± 2.36)			
Change at week 16 (n=208)	-3.74 (± 2.36)			
Change at week 24 (n=208)	-4.41 (± 2.49)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Total Score:Last Observation Carried Forward (LOCF): Period 2

End point title	Mean Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Total Score:Last Observation Carried Forward (LOCF): Period 2

End point description:

BASDAI: 6 questions related to disease activity. Each of first 5 questions was scored by subject on a 100 mm scale ranging from 0 (none) to 100 (very severe), where higher scores indicated more severe disease activity. Sixth question, related to duration of morning stiffness measured on a scale for 0 (0 hours) to 100 (2 hours), where higher scores indicated larger duration of morning stiffness. BASDAI score was obtained by computing mean score for the 2 questions related to morning stiffness (questions 5 [severity of morning stiffness] and 6 [duration of morning stiffness]) and then adding that value to sum of scores for first 4 questions and then dividing total by 5.
BASDAI=(Q1+Q2+Q3+Q4+(Q5+Q6)/2)/5.BASDAI total score ranged from 0 to 10, where higher scores indicated more severe disease activity. Reported values were converted to cm for analysis. FAS for Period 2 was analyzed. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.63 (± 0.66)			
Change at Week 28 from Period 1 Baseline (n=112)	-4.10 (± 2.61)			
Change at Week 28 from Period 2 Baseline (n=112)	1.38 (± 2.27)			
Change at Week 32 from Period 1 Baseline (n=115)	-3.49 (± 2.75)			
Change at Week 32 from Period 2 Baseline (n=115)	1.99 (± 2.57)			
Change at Week 40 from Period 1 Baseline (n=115)	-2.96 (± 2.80)			
Change at Week 40 from Period 2 Baseline (n=115)	2.52 (± 2.76)			
Change at Week 48 from Period 1 Baseline (n=115)	-2.60 (± 2.76)			
Change at Week 48 from Period 2 Baseline (n=115)	2.88 (± 2.77)			
Change at Week 56 from Period 1 Baseline (n=115)	-2.42 (± 2.75)			
Change at Week 56 from Period 2 Baseline (n=115)	3.06 (± 2.76)			
Change at Week 64 from Period 1 Baseline (n=115)	-2.15 (± 2.71)			
Change at Week 64 from Period 2 Baseline (n=115)	3.33 (± 2.82)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Total Score: Last Observation Carried Forward (LOCF): Period 3

End point title	Mean Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Total Score: Last Observation Carried Forward (LOCF): Period 3

End point description:

BASDAI: 6 questions related to disease activity. Each of first 5 questions was scored by subject on a 100 mm scale ranging from 0 (none) to 100 (very severe), where higher scores indicated more severe disease activity. Sixth question, related to duration of morning stiffness measured on a scale for 0 (0 hours) to 100 (2 hours), where higher scores indicated larger duration of morning stiffness. BASDAI score was obtained by computing mean score for the 2 questions related to morning stiffness (questions 5 [severity of morning stiffness] and 6 [duration of morning stiffness]) and then adding that value to sum of scores for first 4 questions and then dividing total by 5.
BASDAI=(Q1+Q2+Q3+Q4+(Q5+Q6)/2)/5.BASDAI total score ranged from 0 to 10, where higher scores indicated more severe disease activity. Reported values were converted to cm for analysis. FAS for Period 3 was analyzed. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects

End point type	Secondary

End point timeframe:

Period 1: Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Period 3: Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=86)	5.53 (± 2.24)			
Change at Week 64 from Period 1 Baseline (n=15)	-0.92 (± 2.82)			
Change at Week 64 from Period 2 Baseline (n=15)	4.63 (± 2.14)			
Change at Week 64 from Period 3 Baseline (n=15)	0.37 (± 1.23)			
Change at Week 68 from Period 1 Baseline (n=86)	-4.01 (± 2.11)			
Change at Week 68 from Period 2 Baseline (n=86)	1.68 (± 1.86)			
Change at Week 68 from Period 3 Baseline (n=86)	-3.20 (± 2.19)			
Change at Week 72 from Period 1 Baseline (n=87)	-4.47 (± 2.11)			
Change at Week 72 from Period 2 Baseline (n=87)	1.22 (± 1.73)			
Change at Week 72 from Period 3 Baseline(n=87)	-3.65 (± 2.33)			
Change at Week 76 from Period 1 Baseline (n=87)	-4.78 (± 2.26)			
Change at Week 76 from Period 2 Baseline (n=87)	0.91 (± 1.51)			
Change at Week 76 from Period 3 Baseline (n=87)	-3.96 (± 2.42)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved at Least 50% Improvement From Baseline in Disease Activity According to Bath Ankylosing Spondylitis Disease Activity Index (BASDAI): Observed Cases (OC): Period 1

End point title	Percentage of Subjects Who Achieved at Least 50% Improvement From Baseline in Disease Activity According to Bath Ankylosing Spondylitis Disease Activity Index (BASDAI): Observed Cases (OC): Period 1

End point description:

50% improvement from baseline in BASDAI: percentage of subjects achieved 50% decrease from baseline in BASDAI total score. BASDAI: 6 questions (Q) related to disease activity. Each of first 5 questions was scored by subject on 100 mm scale, range 0=none to 100=very severe, higher scores = more severe disease activity. Sixth question: duration of morning stiffness, was on scale for 0=0 hours to 100=2 hours, higher scores = larger duration of morning stiffness. BASDAI score obtained by computing mean score for 2 questions related to morning stiffness (Q5 [severity of morning stiffness], Q6 [duration of morning stiffness]) and adding that value to sum of scores for first 4Q and then dividing total by 5. BASDAI=(Q1+Q2+Q3+Q4+(Q5+Q6)/2)/5. BASDAI total score ranged from 0 to 10, higher scores = more severe disease activity. Reported values were converted to cm for analysis. Improvement was relative to baseline. FAS Period 1 was analyzed. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 4 (n=208)	33.7 (27.49 to 40.27)			
Week 8 (n=201)	50.7 (43.87 to 57.61)			
Week 12 (n=198)	57.1 (50.12 to 63.82)			
Week 16 (n=192)	66.7 (59.79 to 73.05)			
Week 24 (n=190)	78.9 (72.74 to 84.28)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved at Least 50% Improvement From Baseline in Disease Activity According to Bath Ankylosing Spondylitis Disease Activity Index (BASDAI): Observed Cases (OC): Period 2

End point title	Percentage of Subjects Who Achieved at Least 50% Improvement From Baseline in Disease Activity According to Bath Ankylosing Spondylitis Disease Activity Index (BASDAI): Observed Cases (OC): Period 2

End point description:

50% improvement from baseline in BASDAI: percentage of subjects achieved 50% decrease from baseline in BASDAI total score. BASDAI: 6 questions (Q) related to disease activity. Each of first 5 questions was scored by subject on 100 mm scale, range 0=none to 100=very severe, higher scores = more severe disease activity. Sixth question: duration of morning stiffness, was on scale for 0=0 hours to 100=2 hours, higher scores = larger duration of morning stiffness. BASDAI score obtained by computing mean score for 2 questions related to morning stiffness (Q5 [severity of morning stiffness], Q6 [duration of morning stiffness]) and adding that value to sum of scores for first 4Q and then dividing total by 5. BASDAI=(Q1+Q2+Q3+Q4+(Q5+Q6)/2)/5. BASDAI total score ranged from 0 to 10, higher scores = more severe disease activity. Reported values were converted to cm for analysis. Improvement was relative to baseline. FAS Period 2 was analyzed. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 2 baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 28 (n=112)	77.7 (69.33 to 84.62)			
Week 32 (n=94)	77.7 (68.48 to 85.16)			
Week 40 (n=69)	73.9 (62.72 to 83.14)			
Week 48 (n=53)	77.4 (64.84 to 86.98)			
Week 56 (n=42)	83.3 (70.04 to 92.22)			
Week 64 (n=34)	76.5 (60.45 to 88.20)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved at Least 50% Improvement From Baseline in Disease Activity According to Bath Ankylosing Spondylitis Disease Activity Index (BASDAI): Observed Cases (OC): Period 3

End point title	Percentage of Subjects Who Achieved at Least 50% Improvement From Baseline in Disease Activity According to Bath Ankylosing Spondylitis Disease Activity Index (BASDAI): Observed Cases (OC): Period 3

End point description:

50% improvement from baseline in BASDAI: percentage of subjects achieved 50% decrease from baseline in BASDAI total score. BASDAI: 6 questions (Q) related to disease activity. Each of first 5 questions was scored by subject on 100 mm scale, range 0=none to 100=very severe, higher scores = more severe disease activity. Sixth question: duration of morning stiffness, was on scale for 0=0 hours to 100=2 hours, higher scores = larger duration of morning stiffness. BASDAI score obtained by computing mean score for 2 questions related to morning stiffness (Q5 [severity of morning stiffness], Q6 [duration of morning stiffness]) and adding that value to sum of scores for first 4Q and then dividing total by 5. BASDAI=(Q1+Q2+Q3+Q4+(Q5+Q6)/2)/5. BASDAI total score ranged from 0 to 10, higher scores = more severe disease activity. Reported values were converted to cm for analysis. Improvement was relative to baseline. FAS Period 3 was analyzed. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 3 baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	20.0 (5.98 to 44.36)			

Week 68 (n=85)	72.9 (62.84 to 81.51)			
Week 72 (n=87)	78.2 (68.65 to 85.83)			
Week 76 (n=85)	84.7 (75.95 to 91.15)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved at Least 50% Improvement From Baseline in Disease Activity According to Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) :Last Observation Carried Forward (LOCF): Period 1

End point title	Percentage of Subjects Who Achieved at Least 50% Improvement From Baseline in Disease Activity According to Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) :Last Observation Carried Forward (LOCF): Period 1

End point description:

50% improvement from baseline in BASDAI: percentage of subjects achieved 50% decrease from baseline in BASDAI total score. BASDAI: 6 questions (Q) related to disease activity. Each of first 5 questions was scored by subject on 100 mm scale, range 0=none to 100=very severe, higher scores = more severe disease activity. Sixth question: duration of morning stiffness, was on scale for 0=0 hours to 100=2 hours, higher scores = larger duration of morning stiffness. BASDAI score obtained by computing mean score for 2 questions related to morning stiffness (Q5 [severity of morning stiffness], Q6 [duration of morning stiffness]) and adding that value to sum of scores for first 4Q and then dividing total by 5. Improvement was relative to baseline. FAS Period 1 was analyzed. Missing data was imputed using mixed LOCF.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	208			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 4	33.7 (27.49 to 40.27)			
Week 8	50.5 (43.72 to 57.23)			
Week 12	55.8 (48.98 to 62.40)			
Week 16	63.9 (57.26 to 70.24)			
Week 24	75.0 (68.80 to 80.51)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved at Least 50% Improvement From Baseline in Disease Activity According to Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) :Last Observation Carried Forward (LOCF): Period 2

End point title	Percentage of Subjects Who Achieved at Least 50% Improvement From Baseline in Disease Activity According to Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) :Last Observation Carried Forward (LOCF): Period 2

End point description:

50% improvement from baseline in BASDAI: percentage of subjects achieved 50% decrease from baseline in BASDAI total score. BASDAI: 6 questions (Q) related to disease activity. Each of first 5 questions was scored by subject on 100 mm scale, range 0=none to 100=very severe, higher scores = more severe disease activity. Sixth question: duration of morning stiffness, was on scale for 0=0 hours to 100=2 hours, higher scores = larger duration of morning stiffness. BASDAI score obtained by computing mean score for 2 questions related to morning stiffness (Q5 [severity of morning stiffness], Q6 [duration of morning stiffness]) and adding that value to sum of scores for first 4Q and then dividing total by 5. Improvement was relative to baseline. FAS Period 2 was analyzed. Missing data was imputed using mixed LOCF. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 2 baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 28 (n=112)	77.7 (69.33 to 84.62)			
Week 32 (n=115)	67.0 (58.02 to 75.05)			
Week 40 (n=115)	57.4 (48.26 to 66.15)			
Week 48 (n=115)	51.3 (42.23 to 60.31)			
Week 56 (n=115)	47.0 (38.01 to 56.06)			
Week 64 (n=115)	41.7 (33.02 to 50.86)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved at Least 50% Improvement From Baseline in Disease Activity According to Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) :Last Observation Carried Forward (LOCF): Period 3

End point title	Percentage of Subjects Who Achieved at Least 50% Improvement From Baseline in Disease Activity According to Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) :Last Observation Carried Forward (LOCF): Period 3

End point description:

50% improvement from baseline in BASDAI: percentage of subjects achieved 50% decrease from baseline in BASDAI total score. BASDAI: 6 questions (Q) related to disease activity. Each of first 5 questions was scored by subject on 100 mm scale, range 0=none to 100=very severe, higher scores = more severe disease activity. Sixth question: duration of morning stiffness, was on scale for 0=0 hours to 100=2 hours, higher scores = larger duration of morning stiffness. BASDAI score obtained by computing mean score for 2 questions related to morning stiffness (Q5 [severity of morning stiffness], Q6 [duration of morning stiffness]) and adding that value to sum of scores for first 4Q and then dividing total by 5. Improvement was relative to baseline. FAS Period 3 was analyzed. Missing data was imputed using mixed LOCF. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 3 baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	20.0 (5.98 to 44.36)			
Week 68 (n=86)	72.1 (62.00 to 80.73)			
Week 72 (n=87)	78.2 (68.65 to 85.83)			
Week 78 (n=87)	82.8 (73.82 to 89.56)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Highly Sensitive C Reactive Protein (hsCRP): Observed Cases (OC): Period 1

End point title	Mean Change From Baseline in Highly Sensitive C Reactive Protein (hsCRP): Observed Cases (OC): Period 1

End point description:

Change from baseline in hsCRP levels were reported. hsCRP is a sensitive laboratory assay for serum levels of C-Reactive Protein, which is a biomarker of inflammation. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: milligram per liter (mg/L)				
arithmetic mean (standard deviation)				
Baseline (n=209)	12.73 (± 20.63)			
Change at week 4 (n=208)	-8.72 (± 19.70)			
Change at week 8 (n=201)	-9.20 (± 19.68)			
Change at week 12 (n=197)	-8.98 (± 19.92)			
Change at week 16 (n=192)	-9.12 (± 20.23)			
Change at week 24 (n=190)	-9.73 (± 19.39)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Highly Sensitive C Reactive Protein (hsCRP): Observed Cases (OC): Period 2

End point title	Mean Change From Baseline in Highly Sensitive C Reactive Protein (hsCRP): Observed Cases (OC): Period 2

End point description:

Change from baseline in hsCRP levels were reported. hsCRP is a sensitive laboratory assay for serum levels of C-Reactive Protein, which is a biomarker of inflammation. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: mg/L				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	1.45 (± 1.54)			
Change at Week 28 from Period 1 Baseline (n=111)	-7.46 (± 15.23)			
Change at Week 28 from Period 2 Baseline (n=111)	2.60 (± 5.76)			
Change at Week 32 from Period 1 Baseline (n=93)	-6.94 (± 16.83)			
Change at Week 32 from Period 2 Baseline(n=93)	4.72 (± 12.31)			

Change at Week 40 from Period 1 Baseline (n=69)	-5.87 (± 13.89)			
Change at Week 40 from Period 2 Baseline| (n=69)	3.04 (± 6.95)			
Change at Week 48 from Period 1 Baseline (n=53)	-5.94 (± 14.65)			
Change at Week 48 from Period 2 Baseline (n=53)	3.29 (± 6.83)			
Change at Week 56 from Period 1 Baseline (n=42)	-6.31 (± 12.65)			
Change at Week 56 from Period 2 Baseline (n=42)	2.29 (± 4.93)			
Change at Week 64 from Period 1 Baseline (n=34)	-6.47 (± 13.43)			
Change at Week 64 from Period 2 Baseline (n=34)	2.38 (± 5.04)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Highly Sensitive C Reactive Protein (hsCRP): Observed Cases (OC): Period 3

End point title	Mean Change From Baseline in Highly Sensitive C Reactive Protein (hsCRP): Observed Cases (OC): Period 3

End point description:

Change from baseline in hsCRP levels were reported. hsCRP is a sensitive laboratory assay for serum levels of C-Reactive Protein, which is a biomarker of inflammation. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: mg/L				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=85)	7.14 (± 11.88)			
Change at Week 64 from Period 1 Baseline (n=15)	-2.58 (± 14.89)			
Change at Week 64 from Period 2 Baseline (n=15)	9.15 (± 21.38)			
Change at Week 64 from Period 3 Baseline (n=14)	1.61 (± 4.68)			
Change at Week 68 from Period 1 Baseline (n=84)	-8.20 (± 16.77)			
Change at Week 68 from Period 2 Baseline (n=84)	0.54 (± 3.11)			

Change at Week 68 from Period 3 Baseline (n=82)	-4.52 (± 9.23)			
Change at Week 72 from Period 1 Baseline (n=86)	-8.21 (± 16.69)			
Change at Week 72 from Period 2 Baseline (n=86)	0.50 (± 4.38)			
Change at Week 72 from Period 3 Baseline (n=84)	-4.46 (± 9.34)			
Change at Week 76 from Period 1 Baseline (n=85)	-7.40 (± 15.98)			
Change at Week 76 from Period 2 Baseline (n=85)	1.39 (± 5.65)			
Change at Week 76 from Period 3 Baseline (n=83)	-3.49 (± 8.27)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Highly Sensitive C Reactive Protein (hsCRP): Last Observation Carried Forward (LOCF): Period 1

End point title	Mean Change From Baseline in Highly Sensitive C Reactive Protein (hsCRP): Last Observation Carried Forward (LOCF): Period 1

End point description:

Change from baseline in hsCRP levels were reported. hsCRP is a sensitive laboratory assay for serum levels of C-Reactive Protein, which is a biomarker of inflammation. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: mg/L				
arithmetic mean (standard deviation)				
Baseline (n=209)	12.73 (± 20.63)			
Change at week 4 (n=208)	-8.72 (± 19.70)			
Change at week 8 (n=208)	-9.14 (± 19.59)			
Change at week 12 (n=208)	-8.77 (± 19.66)			
Change at week 16 (n=208)	-8.72 (± 19.76)			
Change at week 24 (n=208)	-9.28 (± 18.90)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Highly Sensitive C Reactive Protein (hsCRP): Last Observation Carried Forward (LOCF): Period 2

End point title	Mean Change From Baseline in Highly Sensitive C Reactive Protein (hsCRP): Last Observation Carried Forward (LOCF): Period 2

End point description:

Change from baseline in hsCRP levels were reported. hsCRP is a sensitive laboratory assay for serum levels of C-Reactive Protein, which is a biomarker of inflammation. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: mg/L				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	1.45 (± 1.54)			
Change at Week 28 from Period 1 Baseline (n=111)	-7.46 (± 15.23)			
Change at Week 28 from Period 2 Baseline (n=111)	2.60 (± 5.76)			
Change at Week 32 from Period 1 Baseline (n=114)	-5.86 (± 15.73)			
Change at Week 32 from Period 2 Baseline (n=114)	4.46 (± 11.24)			
Change at Week 40 from Period 1 Baseline (n=114)	-5.56 (± 13.91)			
Change at Week 40 from Period 2 Baseline (n=114)	4.76 (± 10.88)			
Change at Week 48 from Period 1 Baseline (n=114)	-4.83 (± 14.26)			
Change at Week 48 from Period 2 Baseline (n=114)	5.49 (± 11.51)			
Change at Week 56 from Period 1 Baseline (n=114)	-5.05 (± 14.01)			
Change at Week 56 from Period 2 Baseline (n=114)	5.27 (± 11.13)			
Change at Week 64 from Period 1 Baseline (n=114)	-4.90 (± 13.88)			

Change at Week 64 from Period 2 Baseline (n=114)	5.42 (± 11.28)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Highly Sensitive C Reactive Protein (hsCRP): Last Observation Carried Forward (LOCF): Period 3

End point title	Mean Change From Baseline in Highly Sensitive C Reactive Protein (hsCRP): Last Observation Carried Forward (LOCF): Period 3

End point description:

Change from baseline in hsCRP levels were reported. hsCRP is a sensitive laboratory assay for serum levels of C-Reactive Protein, which is a biomarker of inflammation. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: mg/L				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=85)	7.14 (± 11.88)			
Change at Week 64 from Period 1 Baseline (n=15)	-2.58 (± 14.89)			
Change at Week 64 from Period 2 Baseline (n=15)	9.15 (± 21.38)			
Change at Week 64 from Period 3 Baseline (n=14)	1.61 (± 4.68)			
Change at Week 68 from Period 1 Baseline (n=85)	-7.98 (± 16.80)			
Change at Week 68 from Period 2 Baseline (n=85)	1.53 (± 9.66)			
Change at Week 68 from Period 3 Baseline (n=83)	-4.32 (± 9.34)			
Change at Week 72 from Period 1 Baseline (n=87)	-7.99 (± 16.71)			
Change at Week 72 from Period 2 Baseline (n=87)	1.47 (± 10.05)			
Change at Week 72 from Period 3 Baseline (n=85)	-4.27 (± 9.45)			
Change at Week 76 from Period 1 Baseline (n=87)	-7.12 (± 15.93)			
Change at Week 76 from Period 2 Baseline (n=87)	2.34 (± 10.56)			

Change at Week 76 from Period 3 Baseline (n=85)	-3.38 (± 8.36)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) VAS score > 82 at Week 12, 24: Observed Cases (OC): Period 1

End point title	Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) VAS score > 82 at Week 12, 24: Observed Cases (OC): Period 1

End point description:

The EQ-5D questionnaire is a health-related quality of life assessment (HRQOL). The EQ-5D questionnaire assesses HRQOL in terms of degree of limitation on 5 health dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) and as overall health using a VAS with response options. Overall EQ 5D VAS score ranged from 0 (worst imaginable health) to 100 (best imaginable health). Lower scores indicate worsening. In this outcome measure, data for percentage of subjects who reached the cut-off value of <82 is reported. This threshold was based on subject's demographic characteristics and population norm. This outcome measure was planned to be analysed at baseline, Week 12 and 24. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Baseline (n=209)	4.3 (2.15 to 7.71)			
Week 12 (n=207)	28.5 (22.68 to 34.92)			
Week 24 (n=191)	50.3 (43.21 to 57.30)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) VAS score > 82 at Week 32, 48, 64: Observed Cases (OC): Period 2

End point title	Percentage of Subjects Who Achieved an European Quality of

	Life-5 Dimensions Health Questionnaire (EQ-5D) VAS score > 82 at Week 32, 48, 64: Observed Cases (OC): Period 2

End point description:

The EQ-5D questionnaire is a HRQOL. The EQ-5D questionnaire assesses HRQOL in terms of degree of limitation on 5 health dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) and as overall health using a VAS with response options. Overall EQ 5D VAS score ranged from 0 (worst imaginable health) to 100 (best imaginable health). Lower scores indicate worsening. In this outcome measure, data for percentage of subjects who reached the cut-off value of <82 is reported. This threshold was based on subject's demographic characteristics and population norm. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 32 (n=107)	43.0 (33.90 to 52.45)			
Week 48 (n=66)	37.9 (26.90 to 49.90)			
Week 64 (n=41)	46.3 (31.76 to 61.42)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) VAS score > 82 at Week 64, 76: Observed Cases (OC): Period 3

End point title	Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) VAS score > 82 at Week 64, 76: Observed Cases (OC): Period 3

End point description:

The EQ-5D questionnaire is a HRQOL. The EQ-5D questionnaire assesses HRQOL in terms of degree of limitation on 5 health dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) and as overall health using a VAS with response options. Overall EQ 5D VAS score ranged from 0 (worst imaginable health) to 100 (best imaginable health). Lower scores indicate worsening. In this outcome measure, data for percentage of subjects who reached the cut-off value of <82 is reported. This threshold was based on subject's demographic characteristics and population norm. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	6.7 (0.73 to 27.18)			
Week 76 (n=86)	50.0 (39.58 to 60.42)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) VAS score > 82 at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point title	Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) VAS score > 82 at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point description:

The EQ-5D questionnaire is a HRQOL. The EQ-5D questionnaire assesses HRQOL in terms of degree of limitation on 5 health dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) and as overall health using a VAS with response options. Overall EQ 5D VAS score ranged from 0 (worst imaginable health) to 100 (best imaginable health). Lower scores indicate worsening. In this outcome measure, data for percentage of subjects who reached the cut-off value of <82 is reported. This threshold was based on subject's demographic characteristics and population norm. This outcome measure was planned to be analyzed at baseline, Week 12 and 24. Missing data was imputed using mixed LOCF. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Baseline (n=209)	4.3 (2.15 to 7.71)			
Week 12 (n=207)	28.5 (22.68 to 34.92)			
Week 24 (n=207)	47.8 (41.09 to 54.62)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) VAS score > 82 at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point title	Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) VAS score > 82 at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point description:

The EQ-5D questionnaire is a HRQOL. The EQ-5D questionnaire assesses HRQOL in terms of degree of limitation on 5 health dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) and as overall health using a VAS with response options. Overall EQ 5D VAS score ranged from 0 (worst imaginable health) to 100 (best imaginable health). Lower scores indicate worsening. In this outcome measure, data for percentage of subjects who reached the cut-off value of <82 is reported. This threshold was based on subject's demographic characteristics and population norm. This outcome measure was planned to be analyzed at baseline, Week 12 and 24. Missing data was imputed using mixed LOCF. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 32 (n=107)	43.0 (33.90 to 52.45)			
Week 48 (n=108)	32.4 (24.14 to 41.61)			
Week 64 (n=108)	28.7 (20.82 to 37.71)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) VAS score > 82 at Week 64, 76: Last

Observation Carried Forward (LOCF): Period 3

End point title	Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) VAS score > 82 at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point description:

The EQ-5D questionnaire is a HRQOL. The EQ-5D questionnaire assesses HRQOL in terms of degree of limitation on 5 health dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) and as overall health using a VAS with response options. Overall EQ 5D VAS score ranged from 0 (worst imaginable health) to 100 (best imaginable health). Lower scores indicate worsening. In this outcome measure, data for percentage of subjects who reached the cut-off value of <82 is reported. This threshold was based on subject's demographic characteristics and population norm. This outcome measure was planned to be analyzed at baseline, Week 12 and 24. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	6.7 (0.73 to 27.18)			
Week 76 (n=86)	50.0 (39.58 to 60.42)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=0.05 Increase from Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Score at Week 12, 24: Observed Cases (OC): Period 1

End point title	Percentage of Subjects With >=0.05 Increase from Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Score at Week 12, 24: Observed Cases (OC): Period 1

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ''worst health condition''. This outcome measure was planned to be analyzed at baseline, Week 12 and 24.Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 12 (n=207)	70.0 (63.56 to 75.98)			
Week 24 (n=191)	79.1 (72.88 to 84.37)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=0.05 Increase from Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Score at Week 32, 48, 64: Observed Cases (OC): Period 2

End point title	Percentage of Subjects With >=0.05 Increase from Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Score at Week 32, 48, 64: Observed Cases (OC): Period 2

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ‘’worst health condition’’. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, “n” signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 32 (n=107)	72.0 (62.95 to 79.81)			
Week 48(n=66)	68.2 (56.35 to 78.46)			
Week 64 (n=41)	75.6 (61.03 to 86.71)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=0.05 Increase from Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index score at Week 64, 76: Observed Cases (OC): Period 3

End point title	Percentage of Subjects With >=0.05 Increase from Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index score at Week 64, 76: Observed Cases (OC): Period 3

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ‘’worst health condition’’. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, “n” signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	53.3 (29.39 to 76.12)			
Week 76 (n=86)	82.6 (73.53 to 89.44)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=0.05 Increase from Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index score at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point title	Percentage of Subjects With >=0.05 Increase from Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index score at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ‘’worst health condition’’. This outcome measure was planned to be analyzed at baseline, Week 12 and 24. Missing data was imputed using mixed LOCF. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline.

End point type	Secondary

End point timeframe:

Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	207			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 12	70.0 (63.56 to 75.98)			
Week 24	76.8 (70.72 to 82.16)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=0.05 Increase from Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index score at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point title	Percentage of Subjects With >=0.05 Increase from Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index score at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ‘‘worst health condition’’. Missing data was imputed using mixed LOCF. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, “n” signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 32 (n=107)	72.0 (62.95 to 79.81)			
Week 48 (n=108)	62.0 (52.66 to 70.77)			
Week 64 (n=108)	61.1 (51.72 to 69.91)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=0.05 Increase from Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index score at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point title	Percentage of Subjects With >=0.05 Increase from Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index score at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ‘’worst health condition’’. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, “n” signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	53.3 (29.39 to 76.12)			
Week 76 (n=86)	82.6 (73.53 to 89.44)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Score of 1 at Week 12, 24: Observed Cases (OC): Period 1

End point title	Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Score of 1 at Week 12, 24: Observed Cases (OC): Period 1

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ‘’worst health condition’’. This outcome measure was planned to be
analyzed at baseline, Week 12 and 24. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, “n” signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Baseline: mobility (n=209)	32.5 (26.46 to 39.09)			
Baseline: self-care (n=209)	64.6 (57.94 to 70.84)			
Baseline: usual activity (n=209)	20.6 (15.52 to 26.44)			
Baseline: pain/discomfort (n=209)	1.9 (0.65 to 4.49)			
Baseline: anxiety/depression (n=209)	37.3 (30.97 to 44.02)			
Week 12: mobility (n=207)	65.2 (58.55 to 71.46)			
Week 12: self-care (n=207)	86.5 (81.32 to 90.62)			
Week 12: usual activity (n=207)	48.3 (41.56 to 55.10)			
Week 12: pain/discomfort (n=207)	25.6 (20.03 to 31.86)			
Week 12: anxiety/depression (n=207)	64.7 (58.06 to 71.00)			
Week 24: mobility (n=191)	80.6 (74.59 to 85.75)			
Week 24: self-care (n=191)	93.2 (88.96 to 96.13)			
Week 24: usual activity (n=191)	64.4 (57.43 to 70.93)			
Week 24: pain/discomfort (n=191)	44.0 (37.07 to 51.06)			
Week 24: anxiety/depression (n=191)	78.0 (71.74 to 83.44)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Score of 1 at Week 32, 48, 64: Observed Cases (OC): Period 2

End point title	Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Score of 1 at Week 32, 48, 64: Observed Cases (OC): Period 2

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ‘‘worst health condition’’. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, “n” signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 32: mobility (n=107)	66.4 (57.06 to 74.78)			
Week 32: self-care (n=107)	83.2 (75.25 to 89.34)			
Week 32: usual activity (n=107)	55.1 (45.68 to 64.32)			
Week 32: pain/discomfort (n=107)	28.0 (20.19 to 37.05)			
Week 32: anxiety/depression (n=107)	70.1 (60.97 to 78.15)			
Week 48: mobility (n=66)	71.2 (59.56 to 81.05)			
Week 48: self-care (n=66)	87.9 (78.43 to 94.10)			
Week 48: usual activity (n=66)	66.7 (54.77 to 77.14)			
Week 48: pain/discomfort (n=66)	31.8 (21.54 to 43.65)			
Week 48: anxiety/depression (n=66)	69.7 (57.95 to 79.76)			
Week 64: mobility (n=41)	68.3 (53.18 to 80.92)			
Week 64: self-care (n=41)	85.4 (72.30 to 93.65)			
Week 64: usual activity (n=41)	63.4 (48.17 to 76.84)			
Week 64: pain/discomfort (n=41)	34.1 (21.10 to 49.35)			
Week 64: anxiety/depression (n=41)	73.2 (58.37 to 84.83)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Score of 1 at Week 64, 76: Observed Cases (OC): Period 3

End point title	Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Score of 1 at Week 64, 76: Observed Cases (OC): Period 3

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ''worst health condition''. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64: mobility (n=15)	26.7 (9.74 to 51.66)			
Week 64: self-care (n=15)	73.3 (48.34 to 90.26)			
Week 64: usual activity (n=15)	26.7 (9.74 to 51.66)			
Week 64: pain/discomfort (n=15)	6.7 (0.73 to 271.8)			
Week 64: anxiety/depression (n=15)	46.7 (23.88 to 70.61)			
Week 76: mobility (n=86)	73.3 (63.24 to 81.73)			
Week 76: self-care (n=86)	93.0 (86.19 to 97.04)			
Week 76: usual activity (n=86)	61.6 (51.10 to 71.38)			
Week 76: pain/discomfort (n=86)	40.7 (30.76 to 51.25)			
Week 76: anxiety/depression (n=86)	75.6 (65.76 to 83.71)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Score of 1 at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point title	Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Score of 1 at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ''worst health condition''. This outcome measure was planned to be analyzed at baseline, Week 12 and 24. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Baseline: mobility (n=209)	32.5 (26.46 to 39.09)			
Baseline: self-care (n=209)	64.6 (57.94 to 70.84)			
Baseline: usual activity (n=209)	20.6 (15.52 to 26.44)			
Baseline: pain/discomfort (n=209)	1.9 (0.65 to 4.49)			
Baseline: anxiety/depression (n=209)	37.3 (30.97 to 44.02)			
Week 12: mobility (n=207)	65.2 (58.55 to 71.46)			
Week 12: self-care(n=207)	86.5 (81.32 to 90.62)			
Week 12: usual activity(n=207)	48.3 (41.56 to 55.10)			
Week 12: pain/discomfort (n=207)	25.6 (20.03 to 31.86)			
Week 12: anxiety/depression (n=207)	64.7 (58.06 to 71.00)			
Week 24: mobility (n=207)	77.3 (71.23 to 82.60)			
Week 24: self-care (n=207)	91.8 (87.46 to 94.95)			
Week 24: usual activity (n=207)	61.4 (54.60 to 67.79)			
Week 24: pain/discomfort (n=207)	41.1 (34.52 to 47.85)			
Week 24: anxiety/depression (n=207)	75.8 (69.68 to 81.29)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Score of 1 at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point title	Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Score of 1 at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ‘’worst health condition’’. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, “n” signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 32: mobility (n=107)	66.4 (57.06 to 74.78)			
Week 32: self-care(n=107)	83.2 (75.25 to 89.34)			
Week 32: usual activity (n=107)	55.1 (45.68 to 64.32)			
Week 32: pain/discomfort (n=107)	28.0 (20.19 to 37.05)			
Week 32: anxiety/depression (n=107)	70.1 (60.97 to 78.15)			
Week 48: mobility (n=108)	57.4 (47.99 to 66.44)			
Week 48: self-care (n=108)	77.8 (69.27 to 84.82)			
Week 48: usual activity (n=108)	51.9 (42.48 to 61.12)			
Week 48: pain/discomfort (n=108)	22.2 (15.18 to 30.73)			
Week 48: anxiety/depression (n=108)	66.7 (57.43 to 75.03)			

Week 64: mobility (n=108)	51.9 (42.48 to 61.12)			
Week 64: self-care (n=108)	72.2 (63.27 to 80.00)			
Week 64: usual activity (n=108)	44.4 (35.32 to 53.86)			
Week 64: pain/discomfort (n=108)	16.7 (10.56 to 24.53)			
Week 64: anxiety/depression (n=108)	65.7 (56.47 to 74.18)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Score of 1 at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point title	Percentage of Subjects Who Achieved an European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Score of 1 at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ‘’worst health condition’’ Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, “n” signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64: mobility (n=15)	26.7 (9.74 to 51.66)			
Week 64: self-care (n=15)	73.3 (48.34 to 90.26)			
Week 64: usual activity (n=15)	26.7 (9.74 to 51.66)			
Week 64: pain/discomfort (n=15)	6.7 (0.73 to 27.18)			
Week 64: anxiety/depression (n=15)	46.7 (23.88 to 70.61)			
Week 76: mobility (n=86)	73.3 (63.24 to 81.73)			
Week 76: self-care(n=86)	93.0 (86.19 to 97.04)			

Week 76: usual activity(n=86)	61.6 (51.10 to 71.38)			
Week 76: pain/discomfort(n=86)	40.7 (30.76 to 51.25)			
Week 76: anxiety/depression(n=86)	75.6 (65.76 to 83.71)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Scores at Week 12, 24: Observed Cases (OC): Period 1

End point title	Change From Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Scores at Week 12, 24: Observed Cases (OC): Period 1

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ‘’worst health condition’’. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, “n” signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=209)	0.42 (± 0.35)			
Change at week 12 (n=207)	0.30 (± 0.35)			
Change at week 24 (n=191)	0.38 (± 0.37)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Scores at Week 32, 48, 64: Observed Cases (OC): Period 2

End point title	Change From Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Scores at Week 32, 48, 64: Observed Cases (OC): Period 2

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point

ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ‘’worst health condition’’. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, “n” signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.89 (± 0.14)			
Change at Week 32 from Period 1 Baseline (n=107)	0.27 (± 0.35)			
Change at Week 32 from Period 2 Baseline (n=107)	-0.15 (± 0.24)			
Change at Week 48 from Period 1 Baseline (n=66)	0.26 (± 0.32)			
Change at Week 48 from Period 2 Baseline (n=66)	-0.13 (± 0.25)			
Change at Week 64 from Period 1 Baseline (n=41)	0.25 (± 0.28)			
Change at Week 64 from Period 2 Baseline (n=41)	-0.12 (± 0.22)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Scores at Week 64, 76: Observed Cases (OC): Period 3

End point title	Change From Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Scores at Week 64, 76: Observed Cases (OC): Period 3

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ‘’worst health condition’’. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, “n” signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=80)	0.55 (± 0.27)			
Change at Week 64 from Period 1 Baseline (n=15)	0.17 (± 0.51)			
Change at Week 64 from Period 2 Baseline (n=15)	-0.29 (± 0.27)			
Change at Week 64 from Period 3 Baseline (n=8)	0.01 (± 0.12)			
Change at Week 76 from Period 1 Baseline (n=86)	0.43 (± 0.37)			
Change at Week 76 from Period 2 Baseline (n=86)	-0.06 (± 0.15)			
Change at Week 76 from Period 3 Baseline (n=80)	0.27 (± 0.31)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Scores at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Scores at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ‘’worst health condition’’. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, “n” signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=209)	0.42 (± 0.35)			
Change at week 12 (n=207)	0.30 (± 0.35)			
Change at week 24 (n=207)	0.37 (± 0.37)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Scores at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Scores at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ‘’worst health condition’’. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, “n” signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.89 (± 0.14)			
Change at Week 32 from Period 1 Baseline (n=107)	0.27 (± 0.35)			
Change at Week 32 from Period 2 Baseline (n=107)	-0.15 (± 0.24)			
Change at Week 48 from Period 1 Baseline (n=108)	0.24 (± 0.33)			
Change at Week 48 from Period 2 Baseline (n=108)	-0.18 (± 0.27)			
Change at Week 64 from Period 1 Baseline (n=108)	0.21 (± 0.30)			
Change at Week 64 from Period 2 Baseline (n=108)	-0.21 (± 0.27)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Scores at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in European Quality of Life-5 Dimensions Health Questionnaire (EQ-5D) Index Scores at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point description:

The EuroQol-5D is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=severe problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "no problem" and 0 representing ‘’worst health condition’’. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, “n” signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Period 3: Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=80)	0.55 (± 0.27)			
Change at Week 64 from Period 1 Baseline (n=15)	0.17 (± 0.51)			
Change at Week 64 from Period 2 Baseline(n=15)	-0.29 (± 0.27)			
Change at Week 64 from Period 3 Baseline (n=8)	0.01 (± 0.12)			
Change at Week 76 from Period 1 Baseline (n=86)	0.43 (± 0.37)			
Change at Week 76 from Period 2 Baseline (n=86)	-0.06 (± 0.15)			
Change at Week 76 from Period 3 Baseline (n=80)	0.27 (± 0.31)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Short Form-36 (SF-36) Physical Component Score (PCS) at Week 12, 24: Observed Cases (OC): Period 1

End point title	Change From Baseline in Short Form-36 (SF-36) Physical Component Score (PCS) at Week 12, 24: Observed Cases (OC): Period 1

End point description:

SF-36: used generic quality of life instrument that assesses subject's general health & functional status. SF-36 consists of 36 questions that grouped into 8 domains(physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health).Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status.Scores of 8 health aspects were summarized to derive 2 component scores (PCS; mental component scores [MCS]). Four domains of the SF-36 comprises PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of MCS score (vitality, social functioning, role-emotional, and mental health). Each PCS and MCS are scored from 0 to 100 with higher scores indicating better health. FAS Period 1: all subjects who took study medication and had one evaluation after baseline."n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n-193)	33.29 (± 7.13)			
Change at week 12 (n=185)	8.84 (± 8.54)			
Change at week 24 (n=173)	12.90 (± 9.30)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Short Form-36 (SF-36) Physical Component Score (PCS) at Week 32, 48, 64: Observed Cases (OC): Period 2

End point title	Change From Baseline in Short Form-36 (SF-36) Physical Component Score (PCS) at Week 32, 48, 64: Observed Cases (OC): Period 2

End point description:

SF-36: used generic quality of life instrument that assesses subject's general health & functional status. SF-36 consists of 36 questions that grouped into 8 domains(physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health).Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive 2 component scores (PCS and MCS). Four domains of the SF-36 comprises PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of MCS score (vitality, social functioning, role-emotional, and mental health). Each PCS and MCS are scored from 0 to 100 with higher scores indicating better health. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=114)	50.03 (± 6.96)			
Change at Week 32 from Period 1 Baseline (n=96)	9.62 (± 10.50)			
Change at Week 32 from Period 2 Baseline (n=102)	-5.97 (± 9.07)			
Change at Week 48 from Period 1 Baseline (n=59)	8.02 (± 9.53)			
Change at Week 48 from Period 2 Baseline (n=64)	-7.84 (± 8.72)			
Change at Week 64 from Period 1 Baseline (n=39)	9.18 (± 9.34)			
Change at Week 64 from Period 2 Baseline (n=40)	-7.17 (± 9.32)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Short Form-36 (SF-36) Physical Component Score (PCS) at Week 64, 76: Observed Cases (OC): Period 3

End point title	Change From Baseline in Short Form-36 (SF-36) Physical Component Score (PCS) at Week 64, 76: Observed Cases (OC): Period 3

End point description:

SF-36:used generic quality of life instrument that assesses subject’s general health & functional status. SF-36 consists of 36 questions that grouped into 8 domains(physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health).Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive 2 component scores (PCS and MCS). Four domains of the SF-36 comprises PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of MCS score (vitality, social functioning, role-emotional, and mental health). Each PCS and MCS are scored from 0 to 100 with higher scores indicating better health. FAS Period 3 included all subjects who took study retreatment medication and had at least 1 evaluation after restarting active therapy. “n”=subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=77)	34.39 (± 7.16)			
Change at Week 64 from Period 1 Baseline (n=14)	-0.81 (± 9.87)			
Change at Week 64 from Period 2 Baseline (n=15)	-16.06 (± 9.61)			
Change at Week 64 from Period 3 Baseline (n=8)	-2.98 (± 3.72)			
Change at Week 76 from Period 1 Baseline (n=74)	11.76 (± 7.84)			
Change at Week 76 from Period 2 Baseline (n=82)	-3.21 (± 5.47)			
Change at Week 76 from Period 3 Baseline (n=73)	11.36 (± 8.61)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Short Form-36 (SF-36) Physical Component Score (PCS) Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in Short Form-36 (SF-36) Physical Component Score (PCS) Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point description:

SF-36: used generic quality of life instrument that assesses subject’s general health & functional status. SF-36 consists of 36 questions that grouped into 8 domains(physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health).Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status.Scores of 8 health aspects were summarized to derive 2 component scores (PCS and MCS).Four domains of the SF-36 comprises PCS score (physical functioning, role-physical, bodily pain, and general health) & remaining 4 domains comprises of MCS score (vitality, social functioning, role-emotional, and mental health). Each PCS and MCS scored from 0 to 100 with higher scores indicating better health. Missing data was imputed using mixed LOCF. FAS Period 1 included all subjects who took study medication and had one evaluation after baseline.“n”=subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=193)	33.29 (± 7.13)			
Change at week 12 (n=185)	8.84 (± 8.54)			
Change at week 24 (n=190)	12.14 (± 9.37)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Short Form-36 (SF-36) Physical Component Score (PCS) at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in Short Form-36 (SF-36) Physical Component Score (PCS) at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point description:

SF-36: used generic quality of life instrument that assesses subject's general health & functional status. SF-36 consists of 36 questions that grouped into 8 domains(physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health).Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive 2 component scores (PCS and MCS).Four domains of the SF-36 comprises PCS score (physical functioning, role-physical, bodily pain, and general health) & remaining 4 domains comprises of MCS score (vitality, social functioning, role-emotional, and mental health). Each PCS and MCS scored from 0 to 100 with higher scores indicating better health. FAS Period 2: all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=114)	50.03 (± 6.96)			
Change at Week 32 from Period 1 Baseline (n=96)	9.62 (± 10.50)			
Change at Week 32 from Period 2 Baseline (n=102)	-5.97 (± 9.07)			
Change at Week 48 from Period 1 Baseline (n=99)	6.52 (± 10.40)			
Change at Week 48 from Period 2 Baseline (n=105)	-9.19 (± 9.37)			
Change at Week 64 from Period 1 Baseline (n=99)	5.52 (± 10.57)			
Change at Week 64 from Period 2 Baseline (n=105)	-10.32 (± 9.64)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Short Form-36 (SF-36) Physical Component Score (PCS) at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in Short Form-36 (SF-36) Physical Component Score (PCS) at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point description:

SF-36: used generic quality of life instrument that assesses subject's general health & functional status. SF-36 consists of 36 questions that grouped into 8 domains(physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health).Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive 2 component scores. Four domains of the SF-36 comprises PCS score (physical functioning, role-physical, bodily pain, and general health) & remaining 4 domains comprises of MCS score (vitality, social functioning, role-emotional, and mental health). Each PCS and MCS scored from 0 to 100 with higher scores indicating better health. FAS Period 3 population was analysed. Missing data was imputed using mixed LOCF. Here, "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=77)	34.39 (± 7.16)			
Change at Week 64 from Period 1 Baseline (n=14)	-0.81 (± 9.87)			
Change at Week 64 from Period 2 Baseline (n=15)	-16.06 (± 9.61)			
Change at Week 64 from Period 3 Baseline (n=8)	-2.98 (± 3.72)			
Change at Week 76 from Period 1 Baseline (n=74)	11.76 (± 7.84)			
Change at Week 76 from Period 2 Baseline (n=82)	-3.21 (± 5.47)			
Change at Week 76 from Period 3 Baseline (n=73)	11.36 (± 8.61)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=2.5 Improvement From Baseline in Short Form-36 (SF-36) Physical Component Score at Week 12, 24: Observed Cases (OC): Period 1

End point title	Percentage of Subjects With >=2.5 Improvement From

	Baseline in Short Form-36 (SF-36) Physical Component Score at Week 12, 24: Observed Cases (OC): Period 1

End point description:

SF-36 is widely used generic quality of life instrument that assesses the subject's general health and functional status. SF-36 consists of 36 questions that grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive the 2 component scores: PCS, MCS. Four domains of the SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health). The improvement was relative to baseline (Day 1). Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 12 (n=197)	73.1 (66.60 to 78.92)			
Week 24 (n=186)	79.6 (73.35 to 84.88)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=2.5 Improvement From Baseline in Short Form-36 (SF-36) Physical Component Score at Week 32, 48, 64: Observed Cases (OC): Period 2

End point title	Percentage of Subjects With >=2.5 Improvement From Baseline in Short Form-36 (SF-36) Physical Component Score at Week 32, 48, 64: Observed Cases (OC): Period 2

End point description:

SF-36 widely used generic quality of life instrument that assesses the subject's general health and functional status. SF-36 consists of 36 questions that grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive the 2 component scores: PCS, MCS. Four domains of the SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health). Improvement was relative to period 2 baseline (last visit before treatment withdrawal). Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 2 baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 32 (n=103)	72.8 (63.68 to 80.69)			
Week 48 (n=64)	70.3 (58.41 to 80.42)			
Week 64 (n=40)	75.0 (60.17 to 86.36)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=2.5 Improvement From Baseline in Short Form-36 (SF-36) Physical Component Score at Week 64, 76: Observed Cases (OC): Period 3

End point title	Percentage of Subjects With >=2.5 Improvement From Baseline in Short Form-36 (SF-36) Physical Component Score at Week 64, 76: Observed Cases (OC): Period 3

End point description:

SF-36: used generic quality of life instrument that assesses the subject's general health and functional status. SF-36 consists of 36 questions that grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive the 2 component scores: PCS, MCS. Four domains of the SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health). Improvement was relative to period 3 baseline (last visit before retreatment). FAS Period 3 population was analysed. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 3 baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	26.7 (9.74 to 51.66)			
Week 76 (n=82)	80.5 (70.94 to 87.93)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=5 Improvement From Baseline in Short Form-36 (SF-36) Physical Component Score at Week 12, 24: Observed Cases (OC): Period 1

End point title	Percentage of Subjects With >=5 Improvement From Baseline in Short Form-36 (SF-36) Physical Component Score at Week 12, 24: Observed Cases (OC): Period 1

End point description:

SF-36: used generic quality of life instrument that assesses the subject's general health and functional status. SF-36 consists of 36 questions that grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive the 2 component scores: PCS, MCS. Four domains of the SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health. Improvement was relative to baseline (Day 1). Missing data was imputed using mixed LOCF. FAS Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 12 (n=197)	62.4 (55.53 to 68.98)			
Week 24 (n=186)	73.7 (67.00 to 79.59)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=5 Improvement From Baseline in Short Form-36 (SF-36) Physical Component Score at Week 32, 48, 64: Observed Cases (OC): Period 2

End point title	Percentage of Subjects With >=5 Improvement From Baseline in Short Form-36 (SF-36) Physical Component Score at Week

	32, 48, 64: Observed Cases (OC): Period 2

End point description:

SF-36: used generic quality of life instrument that assesses the subject's general health and functional status. SF-36 consists of 36 questions that grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive the 2 component scores: PCS, MCS. Four domains of the SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health. Improvement was relative to period 2 baseline(last visit before treatment withdrawal). FAS Period 2: all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. "n"= subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 2 baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 32 (n=103)	65.0 (55.53 to 73.74)			
Week 48 (n=64)	59.4 (47.15 to 70.78)			
Week 64 (n=40)	62.5 (47.05 to 76.21)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=5 Improvement From Baseline in Short Form-36 (SF-36) Physical Component Score at Week 64, 76: Observed Cases (OC): Period 3

End point title	Percentage of Subjects With >=5 Improvement From Baseline in Short Form-36 (SF-36) Physical Component Score at Week 64, 76: Observed Cases (OC): Period 3

End point description:

SF-36: used generic quality of life instrument that assesses the subject's general health and functional status. SF-36 consists of 36 questions that grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive the 2 component scores: PCS, MCS. Four domains of the SF-36 comprises the PCS score and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health. Improvement was relative to period 3 baseline (last visit before retreatment). FAS Period 3: all subjects who took study retreatment medication and had at least 1 evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 3 baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	20.0 (5.98 to 44.36)			
Week 76 (n=82)	74.4 (64.21 to 82.88)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 12, 24: Observed Cases (OC): Period 1

End point title	Change From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 12, 24: Observed Cases (OC): Period 1

End point description:

SF-36: used generic quality of life instrument that assesses the subject's general health and functional status. It consists of 36 questions grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive the 2 component scores: PCS, MCS. Four domains of SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health). Each PCS and MCS are scored from 0 to 100 with higher scores indicating better health (0= worst value and 100= best value). FAS Period 1: all subjects who took study medication and had 1 evaluation after baseline."n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=193)	44.23 (± 10.69)			
Change at week 12 (n=185)	5.24 (± 9.36)			
Change at week 24 (n=173)	9.23 (± 10.52)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 32, 48, 64: Observed Cases (OC): Period 2

End point title	Change From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 32, 48, 64: Observed Cases (OC): Period 2

End point description:

SF-36: used generic quality of life instrument that assesses the subject's general health and functional status. It consists of 36 questions grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive the 2 component scores: PCS, MCS. Four domains of SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health). Each PCS and MCS are scored from 0 to 100 with higher scores indicating better health (0= worst value and 100= best value). FAS Period 2: all subjects who had at least 1 evaluation during period 2. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=114)	55.06 (± 6.33)			
Change at Week 32 from Period 1 Baseline (n=96)	5.71 (± 10.19)			
Change at Week 32 from Period 2 Baseline (n=102)	-3.74 (± 8.00)			
Change at Week 48 from Period 1 Baseline (n=59)	6.36 (± 9.36)			
Change at Week 48 from Period 2 Baseline (n=64)	-3.19 (± 7.68)			
Change at Week 64 from Period 1 Baseline (n=39)	4.99 (± 9.14)			
Change at Week 64 from Period 2 Baseline (n=40)	-3.86 (± 8.39)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 64, 76: Observed Cases (OC): Period 3

End point title	Change From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 64, 76: Observed Cases (OC): Period 3

End point description:

SF-36: used generic quality of life instrument that assesses subject's general health and functional status. It consists of 36 questions grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive 2 component scores: PCS, MCS. Four domains of SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health). PCS and MCS are scored from 0 to 100 with higher scores indicating better health. FAS Period 3: all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=77)	47.95 (± 9.16)			
Change at Week 64 from Period 1 Baseline (n=14)	0.92 (± 8.80)			
Change at Week 64 from Period 2 Baseline (n=15)	-7.66 (± 9.63)			
Change at Week 64 from Period 3 Baseline (n=8)	0.46 (± 4.25)			
Change at Week 76 from Period 1 Baseline (n=74)	8.81 (± 9.87)			
Change at Week 76 from Period 2 Baseline (n=82)	-2.13 (± 7.00)			
Change at Week 76 from Period 3 Baseline (n=73)	4.24 (± 7.61)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 12, 24: Last Observation

	Carried Forward (LOCF): Period 1

End point description:

SF-36: used generic quality of life instrument that assesses subject's general health and functional status. It consists of 36 questions grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive 2 component scores: PCS, MCS. Four domains of SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health). PCS and MCS are scored from 0 to 100 with higher scores indicating better health. FAS Period 1: all subjects who took study medication and had 1 evaluation after baseline. Missing data was imputed using mixed LOCF. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=193)	44.23 (± 10.69)			
Change at week 12 (n=185)	5.24 (± 9.36)			
Change at week 24 (n=190)	8.39 (± 10.69)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point description:

SF-36: used generic quality of life instrument that assesses subject's general health and functional status. It consists of 36 questions grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive 2 component scores: PCS, MCS. Four domains of SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health). PCS and MCS are scored from 0 to 100 with higher scores indicating better health. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=114)	55.06 (± 6.33)			
Change at Week 32 from Period 1 Baseline (n=96)	5.71 (± 10.19)			
Change at Week 32 from Period 2 Baseline (n=102)	-3.74 (± 8.00)			
Change at Week 48 from Period 1 Baseline (n=99)	5.83 (± 9.15)			
Change at Week 48 from Period 2 Baseline (n=105)	-3.99 (± 8.14)			
Change at Week 64 from Period 1 Baseline (n=99)	5.17 (± 9.15)			
Change at Week 64 from Period 2 Baseline (n=105)	-4.84 (± 8.31)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point description:

SF-36: used generic quality of life instrument that assesses subject's general health and functional status. It consists of 36 questions grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive 2 component scores: PCS, MCS. Four domains of SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health). PCS and MCS are scored from 0 to 100 with higher scores indicating better health. FAS Period 3 population was analysed. Missing data was imputed using mixed LOCF. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=77)	47.95 (± 9.16)			
Change at Week 64 from Period 1 Baseline (n=14)	0.92 (± 8.80)			
Change at Week 64 from Period 2 Baseline (n=15)	-7.66 (± 9.63)			
Change at Week 64 from Period 3 Baseline (n=8)	0.46 (± 4.25)			
Change at Week 76 from Period 1 Baseline (n=74)	8.81 (± 9.87)			
Change at Week 76 from Period 2 Baseline (n=82)	-2.13 (± 7.00)			
Change at Week 76 from Period 3 Baseline (n=73)	4.24 (± 7.61)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=2.5 Improvement From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 12, 24: Observed Cases (OC): Period 1

End point title	Percentage of Subjects With >=2.5 Improvement From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 12, 24: Observed Cases (OC): Period 1

End point description:

SF-36: used generic quality of life instrument that assesses subject's general health and functional status. It consists of 36 questions grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive 2 component scores: PCS, MCS. Four domains of SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health). PCS and MCS are scored from 0 to 100 with higher scores indicating better health. Improvement was relative to baseline (Day 1). FAS Period 1: all subjects who took study medication and had 1 evaluation after baseline. Here, "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 12 (n=197)	52.8 (45.82 to 59.68)			

Week 24 (n=186)	67.2 (60.23 to 73.65)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=2.5 Improvement From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 32, 48, 64: Observed Cases (OC): Period 2

End point title	Percentage of Subjects With >=2.5 Improvement From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 32, 48, 64: Observed Cases (OC): Period 2

End point description:

SF-36: used generic quality of life instrument that assesses subject's general health and functional status. It consists of 36 questions grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive 2 component scores: PCS, MCS. Four domains of SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health). PCS and MCS are scored from 0 to 100 with higher scores indicating better health. FAS for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 2 baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 32 (n=103)	59.2 (49.59 to 68.35)			
Week 48 (n=64)	54.7 (42.51 to 66.45)			
Week 64 (n=40)	60.0 (44.56 to 74.05)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=2.5 Improvement From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 64, 76: Observed Cases (OC): Period 3

End point title	Percentage of Subjects With >=2.5 Improvement From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 64, 76: Observed Cases (OC): Period 3

End point description:

SF-36: used generic quality of life instrument that assesses subject's general health and functional status. It consists of 36 questions grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive 2 component scores: PCS, MCS. Four domains of SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health). PCS and MCS are scored from 0 to 100 with higher scores indicating better health. FAS Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 3 baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	26.7 (9.74 to 51.66)			
Week 76 (n=82)	64.6 (53.92 to 74.33)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=5 Improvement From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 12, 24: Observed Cases (OC): Period 1

End point title	Percentage of Subjects With >=5 Improvement From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 12, 24: Observed Cases (OC): Period 1

End point description:

SF-36 is widely used generic quality of life instrument that assesses subject's general health and functional status. SF-36 consists 36 questions that grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status. Scores of 8 health aspects summarized to derive he 2 component scores: PCS, MCS. 4 domains of SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of MCS score (vitality, social functioning, role-emotional, and mental health). PCS and MCS are scored from 0 to 100 with higher scores indicating better health. Improvement was relative to baseline (Day 1). FAS Period 1:all subjects who took study medication and had one evaluation after baseline."n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 12 (n=197)	45.2 (38.34 to 52.16)			
Week 24 (n=186)	59.7 (52.52 to 66.53)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=5 Improvement From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 32, 48, 64: Observed Cases (OC):Period 2

End point title	Percentage of Subjects With >=5 Improvement From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 32, 48, 64: Observed Cases (OC):Period 2

End point description:

SF-36 is widely used generic quality of life instrument that assesses subject's general health and functional status. It consists 36 questions grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status. Scores of 8 health aspects summarized to derive he 2 component scores: PCS, MCS. 4 domains of SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of MCS score (vitality, social functioning, role-emotional, and mental health). Each PCS and MCS are scored from 0 to 100 with higher scores indicating better health. Improvement was relative to period 2 baseline. FAS Period 2: all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 2 baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 32 (n=103)	48.5 (39.04 to 58.12)			
Week 48 (n=64)	45.3 (33.55 to 57.49)			
Week 64 (n=40)	40.0 (25.95 to 55.44)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >=5 Improvement From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 64, 76: Observed Cases (OC): Period 3

End point title	Percentage of Subjects With >=5 Improvement From Baseline in Short Form-36 (SF-36) Mental Component Score (MCS) at Week 64, 76: Observed Cases (OC): Period 3

End point description:

SF-36 : generic quality of life instrument that assesses subject's general health and functional status. It consists of 36 questions grouped into 8 domains (physical functioning, vitality, social functioning, mental health, role physical, bodily pain, role emotional and general health). Domain scores range from 0 (worst value) to 100 (best value), with greater scores reflecting better health status. Scores of 8 health aspects were summarized to derive the 2 component scores: PCS, MCS. Four domains of the SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and remaining 4 domains comprises of the MCS score (vitality, social functioning, role-emotional, and mental health). Improvement was relative to period 3 baseline. FAS Period 3: all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 3 baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: percentage of subjects				
number (confidence interval 95%)				
Week 64 (n=15)	6.7 (0.73 to 27.18)			
Week 76 (n=82)	56.1 (45.30 to 66.47)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Work Productivity and Activity Impairment (WPAI): Observed Cases (OC): Period 1

End point title	Change From Baseline in Work Productivity and Activity Impairment (WPAI): Observed Cases (OC): Period 1

End point description:

WPAI assesses work productivity and impairment. It is a 6-item questionnaire used to assess degree to which a specified health problem here "AS" affected work attendance, work productivity and productivity in non-work regular activities. Subjects were asked to consider past 7 days prior to each questionnaire day. Questionnaire asks: current employment status, hours worked, hours missed from work for any reason other than AS, hours missed from work due to AS, degree to which AS affected work productivity, and degree to a which AS affected non-work regular activities. 4 component scores were then calculated: percent work time missed due to AS; percent impairment while working due to AS, percent overall work impairment due to AS, and percent non-work activity impairment due to AS. Computed range for each sub-scale was from 0-100, with higher numbers indicating greater impairment and less productivity. FAS Period 1 was analysed. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=140)	50.79 (± 28.13)			
Change at week 4 (n=133)	-15.19 (± 23.82)			
Change at week 8 (n=125)	-21.44 (± 27.58)			
Change at week 12 (n=115)	-21.83 (± 30.13)			
Change at week 16 (n=120)	-27.58 (± 27.62)			
Change at week 24 (n=118)	-35.08 (± 27.14)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Work Productivity and Activity Impairment (WPAI): Observed Cases (OC): Period 2

End point title	Change From Baseline in Work Productivity and Activity Impairment (WPAI): Observed Cases (OC): Period 2

End point description:

WPAI assesses work productivity and impairment. It is a 6-item questionnaire used to assess degree to which a specified health problem here "AS" affected work attendance, work productivity and productivity in non-work regular activities. Subjects were asked to consider past 7 days prior to each questionnaire day. Questionnaire asks: current employment status, hours worked, hours missed from work for any reason other than AS, hours missed from work due to AS, degree to which AS affected work productivity, and degree to a which AS affected non-work regular activities. 4 component scores were then calculated: percent work time missed due to AS; percent impairment while working due to AS, percent overall work impairment due to AS, and percent non-work activity impairment due to AS. Computed range for each sub-scale was from 0-100, with higher numbers indicating greater impairment and less productivity. FAS Period 2 was analysed. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=92)	10.11 (± 13.05)			
Change at Week 28 from Period 1 Baseline (n=77)	-31.56 (± 32.37)			
Change at Week 28 from Period 2 Baseline (n=83)	6.87 (± 18.67)			
Change at Week 32 from Period 1 Baseline (n=60)	-31.00 (± 30.35)			
Change at Week 32 from Period 2 Baseline (n=66)	9.70 (± 19.21)			
Change at Week 40 from Period 1 Baseline (n=49)	-25.71 (± 32.40)			
Change at Week 40 from Period 2 Baseline (n=51)	14.12 (± 24.99)			
Change at Week 48 from Period 1 Baseline (n=35)	-22.86 (± 31.58)			
Change at Week 48 from Period 2 Baseline (n=36)	20.56 (± 26.07)			
Change at Week 56 from Period 1 Baseline (n=28)	-32.14 (± 30.11)			
Change at Week 56 from Period 2 Baseline (n=31)	6.77 (± 21.35)			
Change at Week 64 from Period 1 Baseline (n=24)	-19.17 (± 26.53)			
Change at Week 64 from Period 2 Baseline (n=26)	20.77 (± 37.19)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Work Productivity and Activity Impairment (WPAI): Observed Cases (OC): Period 3

End point title	Change From Baseline in Work Productivity and Activity Impairment (WPAI): Observed Cases (OC): Period 3

End point description:

WPAI assesses work productivity and impairment. It is a 6-item questionnaire used to assess degree to which a specified health problem here "AS" affected work attendance, work productivity and productivity in non-work regular activities. Subjects were asked to consider past 7 days prior to each questionnaire day. Questionnaire asks: current employment status, hours worked, hours missed from work for any reason other than AS, hours missed from work due to AS, degree to which AS affected work productivity, and degree to a which AS affected non-work regular activities. 4 component scores were then calculated: percent work time missed due to AS; percent impairment while working due to AS, percent overall work impairment due to AS, and percent non-work activity impairment due to AS.

Computed range for each sub-scale was from 0-100, with higher numbers indicating greater impairment and less productivity. FAS Period 3 was analysed. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=67)	45.37 (± 29.20)			
Change at Week 64 from Period 1 Baseline (n=10)	8.00 (± 33.93)			
Change at Week 64 from Period 2 Baseline (n=11)	43.64 (± 22.48)			
Change at Week 64 from Period 3 Baseline (n=10)	13.00 (± 30.57)			
Change at Week 68 from Period 1 Baseline (n=57)	-26.32 (± 30.86)			
Change at Week 68 from Period 2 Baseline (n=60)	13.67 (± 22.09)			
Change at Week 68 from Period 3 Baseline (n=60)	-22.83 (± 25.78)			
Change at Week 72 from Period 1 Baseline (n=59)	-32.03 (± 29.58)			
Change at Week 72 from Period 2 Baseline (n=64)	7.97 (± 18.10)			
Change at Week 72 from Period 3 Baseline (n=63)	-29.05 (± 23.88)			
Change at Week 76 from Period 1 Baseline (n=59)	-34.41 (± 27.68)			
Change at Week 76 from Period 2 Baseline (n=62)	6.45 (± 13.92)			
Change at Week 76 from Period 3 Baseline (n=61)	-30.49 (± 26.55)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Work Productivity and Activity Impairment (WPAI): Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in Work Productivity and Activity Impairment (WPAI): Last Observation Carried Forward (LOCF): Period 1

End point description:

WPAI assesses work productivity and impairment.6-item questionnaire used to assess degree to which a specified health problem here "AS" affected work attendance, WP and productivity in non-work regular activities. Subjects were asked to consider past 7 days prior to each questionnaire day. Questionnaire asks: current employment status, hours worked, hours missed from work for any reason other than AS,

hours missed from work due to AS, degree to which AS affected work productivity, degree to a which AS affected non-work regular activities. 4 component scores were then calculated: percent work time missed due to AS; percent impairment while working due to AS, percent overall work impairment due to AS, and percent non-work activity impairment due to AS. Computed range for each sub-scale was from 0-100,higher numbers indicating greater impairment and less productivity. Missing data was imputed using mixed LOCF.FAS Period 1 was analysed. "n"=subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=140)	50.79 (± 28.13)			
Change at week 4 (n=133)	-15.19 (± 23.82)			
Change at week 8 (n=136)	-21.25 (± 27.36)			
Change at week 12 (n=137)	-20.44 (± 29.18)			
Change at week 16 (n=137)	-24.53 (± 28.31)			
Change at week 24 (n=137)	-29.93 (± 29.27)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Work Productivity and Activity Impairment (WPAI): Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in Work Productivity and Activity Impairment (WPAI): Last Observation Carried Forward (LOCF): Period 2

End point description:

WPAI assesses work productivity and impairment.6-item questionnaire used to assess degree to which a specified health problem here "AS" affected work attendance, WP and productivity in non-work regular activities. Subjects were asked to consider past 7 days prior to each questionnaire day. Questionnaire asks: current employment status, hours worked, hours missed from work for any reason other than AS, hours missed from work due to AS, degree to which AS affected work productivity, degree to a which AS affected non-work regular activities. 4 component scores were then calculated: percent work time missed due to AS; percent impairment while working due to AS, percent overall work impairment due to AS, and percent non-work activity impairment due to AS. Computed range for each sub-scale was from 0-100,higher numbers indicating greater impairment and less productivity. Missing data was imputed using mixed LOCF.FAS Period 2 was analysed. "n"=subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=92)	10.11 (± 13.05)			
Change at Week 28 from Period 1 Baseline (n=77)	-31.56 (± 32.37)			
Change at Week 28 from Period 2 Baseline (n=83)	6.87 (± 18.67)			
Change at Week 32 from Period 1 Baseline (n=79)	-24.94 (± 34.34)			
Change at Week 32 from Period 2 Baseline (n=85)	13.41 (± 21.36)			
Change at Week 40 from Period 1 Baseline (n=79)	-19.87 (± 35.68)			
Change at Week 40 from Period 2 Baseline (n=85)	18.12 (± 24.76)			
Change at Week 48 from Period 1 Baseline (n=79)	-17.22 (± 35.26)			
Change at Week 48 from Period 2 Baseline (n=85)	20.71 (± 25.49)			
Change at Week 56 from Period 1 Baseline (n=79)	-17.97 (± 35.13)			
Change at Week 56 from Period 2 Baseline (n=87)	19.43 (± 25.76)			
Change at Week 64 from Period 1 Baseline(n=79)	-12.91 (± 33.97)			
Change at Week 64 from Period 2 Baseline (n=87)	25.06 (± 29.49)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Work Productivity and Activity Impairment (WPAI): Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in Work Productivity and Activity Impairment (WPAI): Last Observation Carried Forward (LOCF): Period 3

End point description:

WPAI assesses work productivity and impairment.6-item questionnaire used to assess degree to which a specified health problem here "AS" affected work attendance, WP and productivity in non-work regular activities. Subjects were asked to consider past 7 days prior to each questionnaire day. Questionnaire asks: current employment status, hours worked, hours missed from work for any reason other than AS, hours missed from work due to AS, degree to which AS affected work productivity, degree to a which AS affected non-work regular activities. 4 component scores were then calculated: percent work time missed due to AS; percent impairment while working due to AS, percent overall work impairment due to AS, and percent non-work activity impairment due to AS. Computed range for each sub-scale was from 0-100,higher numbers indicating greater impairment and less productivity. Missing data was imputed using mixed LOCF.FAS Period 3 was analysed. "n"=subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=67)	45.37 (± 29.20)			
Change at Week 64 from Period 1 Baseline (n=10)	8.00 (± 33.93)			
Change at Week 64 from Period 2 Baseline (n=11)	43.64 (± 22.48)			
Change at Week 64 from Period 3 Baseline (n=10)	13.00 (± 30.57)			
Change at Week 68 from Period 1 Baseline (n=59)	-25.25 (± 30.98)			
Change at Week 68 from Period 2 Baseline (n=63)	14.92 (± 22.35)			
Change at Week 68 from Period 3 Baseline (n=63)	-22.06 (± 25.41)			
Change at Week 72 from Period 1 Baseline (n=60)	-31.67 (± 29.47)			
Change at Week 72 from Period 2 Baseline (n=65)	8.46 (± 18.39)			
Change at Week 72 from Period 3 Baseline (n=64)	-28.44 (± 24.18)			
Change at Week 76 from Period 1 Baseline (n=60)	-33.83 (± 27.81)			
Change at Week 76 from Period 2 Baseline (n=65)	6.46 (± 13.74)			
Change at Week 76 from Period 3 Baseline (n=64)	-29.69 (± 26.24)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Spondyloarthritis Research Consortium of Canada [SPARCC] Score) at Week 24: Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Spondyloarthritis Research Consortium of Canada [SPARCC] Score) at Week 24: Last Observation Carried Forward (LOCF): Period 1

End point description:

Change from baseline in MRI score of spine was assessed using SPARCC method. Scoring was based on 6 consecutive coronal slices from posterior to anterior. Each joint was divided into 4 quadrants. Each quadrant was assigned score of 0=no lesion or 1=increased signal. This part of coring allows for total score ranging from 0-8 for 2 joints of one coronal slice. For each slice, score was increased by 1 for each joint that exhibits an intense signal in any quadrant (thereby allowing for an increase of up to 2 points in

total score for each slice). Also, for each slice, an additional score of 1 was given for each joint that includes a lesion demonstrating continuous increased signal of depth >=1 cm from articular surface (thereby allowing for an additional increase of up to 2 points for each slice). FAS Period 1: all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF.“n” = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=204) Change at week 24 (n=143)	8.48 (± 12.83) -6.08 (± 11.71)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Spondyloarthritis Research Consortium of Canada [SPARCC] Score) at Week 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Spondyloarthritis Research Consortium of Canada [SPARCC] Score) at Week 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point description:

Change from baseline in MRI score of spine was assessed using SPARCC method. Scoring was based on 6 consecutive coronal slices from posterior to anterior. Each joint was divided into 4 quadrants. Each quadrant was assigned score of 0=no lesion or 1=increased signal. This part of coring allows for total score ranging from 0-8 for 2 joints of one coronal slice. For each slice, score was increased by 1 for each joint that exhibits an intense signal in any quadrant (thereby allowing for an increase of up to 2 points in total score for each slice). Also, for each slice, an additional score of 1 was given for each joint that includes a lesion demonstrating continuous increased signal of depth >=1 cm from articular surface. Total minimum and maximum score for all joints across 6 slices was 0 to 72 where higher scores reflecting worse disease. FAS Period 2 was analysed. Missing data was imputed using mixed LOCF. “n” = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=68)	2.41 (± 3.59)			
Change at Week 48 from Period 1 Baseline (n=53)	-6.04 (± 12.99)			
Change at Week 48 from Period 2 Baseline (n=29)	2.07 (± 5.32)			
Change at Week 64 from Period 1 Baseline (n=37)	-6.81 (± 13.74)			
Change at Week 64 from Period 2 Baseline (n=29)	1.45 (± 4.43)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Spondyloarthritis Research Consortium of Canada [SPARCC] Score) at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Spondyloarthritis Research Consortium of Canada [SPARCC] Score) at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point description:

Change from baseline in MRI score of spine was assessed using SPARCC method. Scoring was based on 6 consecutive coronal slices from posterior to anterior. Each joint was divided into 4 quadrants. Each quadrant was assigned score of 0=no lesion or 1=increased signal. This part of coring allows for total score ranging from 0-8 for 2 joints of one coronal slice. For each slice, score was increased by 1 for each joint that exhibits an intense signal in any quadrant (thereby allowing for an increase of up to 2 points in total score for each slice). Also, for each slice, an additional score of 1 was given for each joint that includes a lesion demonstrating continuous increased signal of depth >=1 cm from articular surface. Total minimum and maximum score for all joints across 6 slices was 0 to 72 where higher scores reflecting worse disease. FAS Period 3 was analysed. Missing data was imputed using mixed LOCF. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=50)	3.98 (± 7.28)			
Change at Week 64 from Period 1 Baseline (n=6)	-5.17 (± 8.16)			
Change at Week 64 from Period 2 Baseline (n=4)	2.00 (± 3.37)			

Change at Week 64 from Period 3 Baseline (n=4)	4.75 (± 11.53)			
Change at Week 76 from Period 1 Baseline (n=78)	-8.44 (± 12.92)			
Change at Week 76 from Period 2 Baseline (n=44)	-1.41 (± 3.28)			
Change at Week 76 from Period 3 Baseline (n=46)	-1.96 (± 8.84)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Spondyloarthritis Research Consortium of Canada [SPARCC] Score) at Week 24: Observed Cases (OC): Period 1

End point title	Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Spondyloarthritis Research Consortium of Canada [SPARCC] Score) at Week 24: Observed Cases (OC): Period 1

End point description:

Change from baseline in MRI score of spine assessed using SPARCC. Scoring based on 6 consecutive coronal slices from posterior to anterior. Each joint was divided into 4 quadrants. Each quadrant was assigned score of 0=no lesion or 1=increased signal. This part of coring allows for total score ranging from 0-8 for 2 joints of one coronal slice. For each slice, score was increased by 1 for each joint that exhibits an intense signal in any quadrant (thereby allowing for an increase of up to 2 points in total score for each slice). Also, for each slice, an additional score of 1 was given for each joint that includes a lesion demonstrating continuous increased signal of depth >=1 cm from articular surface. Total minimum and maximum score for all joints across 6 slices was 0 to 72 where higher scores reflecting worse disease. FAS Period 1: all subjects who took study medication and had 1 evaluation after baseline. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=204)	8.48 (± 12.83)			
Change at week 24 (n=143)	-6.08 (± 11.71)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Spondyloarthritis Research Consortium of Canada [SPARCC] Score) at Week

48, 64: Observed Cases (OC): Period 2

End point title	Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Spondyloarthritis Research Consortium of Canada [SPARCC] Score) at Week 48, 64: Observed Cases (OC): Period 2

End point description:

Change from baseline in MRI score of spine assessed using SPARCC. Scoring based on 6 consecutive coronal slices from posterior to anterior. Each joint was divided into 4 quadrants. Each quadrant was assigned score of 0=no lesion or 1=increased signal. This part of coring allows for total score ranging from 0-8 for 2 joints of one coronal slice. For each slice, score was increased by 1 for each joint that exhibits an intense signal in any quadrant (thereby allowing for an increase of up to 2 points in total score for each slice). Also, for each slice, an additional score of 1 was given for each joint that includes a lesion demonstrating continuous increased signal of depth >=1 cm from articular surface. Total minimum and maximum score for all joints across 6 slices was 0 to 72 where higher scores reflecting worse disease. FAS Period 2 :all subjects who had at least one evaluation during period 2. "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=68)	2.41 (± 3.59)			
Change at Week 48 from Period 1 Baseline (n=53)	-6.04 (± 12.99)			
Change at Week 48 from Period 2 Baseline (n=29)	2.07 (± 5.32)			
Change at Week 64 from Period 1 Baseline (n=27)	-5.96 (± 13.83)			
Change at Week 64 from Period 2 Baseline (n=19)	0.37 (± 1.12)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Spondyloarthritis Research Consortium of Canada [SPARCC] Score) at Week 64, 76: Observed Cases (OC): Period 3

End point title	Change From Baseline in Magnetic Resonance Imaging (MRI) of the Spine (Spondyloarthritis Research Consortium of Canada [SPARCC] Score) at Week 64, 76: Observed Cases (OC): Period 3

End point description:

Change from baseline in MRI score of spine assessed using SPARCC. Scoring based on 6 consecutive coronal slices from posterior to anterior. Each joint was divided into 4 quadrants. Each quadrant was assigned score of 0=no lesion or 1=increased signal. This part of coring allows for total score ranging from 0-8 for 2 joints of one coronal slice. For each slice, score was increased by 1 for each joint that exhibits an intense signal in any quadrant (thereby allowing for an increase of up to 2 points in total

score for each slice). Also, for each slice, an additional score of 1 was given for each joint that includes a lesion demonstrating continuous increased signal of depth >=1 cm from articular surface. Total minimum and maximum score for all joints across 6 slices was 0 to 72 where higher scores reflecting worse disease. FAS Period 3 population was analysed. Here, "n" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=50)	3.98 (± 7.28)			
Change at Week 64 from Period 1 Baseline (n=6)	-5.17 (± 8.16)			
Change at Week 64 from Period 2 Baseline (n=4)	-2.00 (± 3.37)			
Change at Week 64 from Period 3 Baseline (n=4)	4.75 (± 11.53)			
Change at Week 76 from Period 1 Baseline (n=78)	-8.44 (± 12.92)			
Change at Week 76 from Period 2 Baseline (n=44)	-1.41 (± 3.28)			
Change at Week 76 from Period 3 Baseline (n=46)	-1.96 (± 8.84)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Ankylosing Spondylitis Disease Activity Score (ASDAS) Inactive Disease After Re-treatment in Period 3

End point title	Time to Ankylosing Spondylitis Disease Activity Score (ASDAS) Inactive Disease After Re-treatment in Period 3

End point description:

Time to ASDAS inactive disease was defined as the time from first dose of retreatment until the first observed event of ASDAS inactive disease. Inactive disease is defined as an ASDAS score <1.3. for ASDAS-CRP or ASDAS score of >=2.1 for ASDAS-ESR. Subjects who did not achieve ASDAS inactive disease were censored at the time of the last ASDAS evaluation in the interval. The full analysis set for retreatment period included all subjects who took study retreatment medication and had at least 1 evaluation after restarting active therapy.

End point type	Secondary

End point timeframe:

Within 12 weeks of Period 3 (retreatment period from Week 64 to 76)

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: weeks				
median (confidence interval 95%)	5.1 (4.29 to 8.14)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Subject Assessment of Disease Activity (SADA) Visual Analogue Scale (VAS): Observed Cases (OC): Period 1

End point title	Change From Baseline in Subject Assessment of Disease Activity (SADA) Visual Analogue Scale (VAS): Observed Cases (OC): Period 1

End point description:

Subjects assessed their overall disease activity over the last 48 hours by using a 100 mm pain scale that ranges from 0 mm (none) to 100 mm (severe pain), where higher scores indicated more pain. The reported values then converted to cm for analysis purposes. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: cm				
arithmetic mean (standard deviation)				
Baseline (n=209)	6.34 (± 2.14)			
Change at week 4 (n=208)	-2.48 (± 2.45)			
Change at week 8 (n=201)	-3.06 (± 2.71)			
Change at week 12 (n=198)	-3.44 (± 2.74)			
Change at week 16 (n=192)	-3.90 (± 2.74)			
Change at week 24 (n=190)	-4.72 (± 2.71)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Subject Assessment of Disease Activity (SADA) Visual Analogue Scale (VAS): Observed Cases (OC): Period 2

End point title	Change From Baseline in Subject Assessment of Disease Activity (SADA) Visual Analogue Scale (VAS): Observed Cases

	(OC): Period 2

End point description:

Subjects assessed their overall disease activity over the last 48 hours by using a 100 mm pain scale that ranges from 0 mm (none) to 100 mm (severe pain), where higher scores indicated more pain. The reported values then converted to cm for analysis purposes. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: cm				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.61 (± 0.57)			
Change at Week 28 from Period 1 Baseline (n=112)	-4.08 (± 3.01)			
Change at Week 28 from Period 2 Baseline (n=112)	1.46 (± 2.47)			
Change at Week 32 from Period 1 Baseline (n=94)	-3.87 (± 3.07)			
Change at Week 32 from Period 2 Baseline (n=94)	1.68 (± 2.49)			
Change at Week 40 from Period 1 Baseline (n=69)	-3.62 (± 2.90)			
Change at Week 40 from Period 2 Baseline (n=69)	1.74 (± 2.47)			
Change at Week 48 from Period 1 Baseline (n=53)	-3.65 (± 2.73)			
Change at Week 48 from Period 2 Baseline (n=53)	1.81 (± 2.70)			
Change at Week 56 from Period 1 Baseline (n=42)	-3.67 (± 2.63)			
Change at Week 56 from Period 2 Baseline(n=42)	1.48 (± 2.45)			
Change at Week 64 from Period 1 Baseline (n=34)	-3.07 (± 3.01)			
Change at Week 64 from Period 2 Baseline (n=34)	1.66 (± 2.95)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Subject Assessment of Disease Activity (SADA) Visual Analogue Scale (VAS): Observed Cases (OC): Period 3

End point title	Change From Baseline in Subject Assessment of Disease Activity (SADA) Visual Analogue Scale (VAS): Observed Cases (OC): Period 3

End point description:

Subjects assessed their overall disease activity over the last 48 hours by using a 100 mm pain scale that ranges from 0 mm (none) to 100 mm (severe pain), where higher scores indicated more pain. The reported values then converted to cm for analysis purposes. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: cm				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=87)	6.27 (± 2.24)			
Change at Week 64 from Period 1 Baseline (n=15)	-0.26 (± 4.09)			
Change at Week 64 from Period 2 Baseline (n=15)	4.95 (± 2.35)			
Change at Week 64 from Period 3 Baseline (n=15)	0.67 (± 2.48)			
Change at Week 68 from Period 1 Baseline (n=85)	1.63 (± 1.90)			
Change at Week 68 from Period 2 Baseline (n=85)	-4.09 (± 2.63)			
Change at Week 68 from Period 3 Baseline (n=85)	-4.09 (± 2.63)			
Change at Week 72 from Period 1 Baseline (n=87)	-4.60 (± 2.59)			
Change at Week 72 from Period 2 Baseline (n=87)	1.23 (± 1.87)			
Change at Week 72 from Period 3 Baseline (n=87)	-4.44 (± 2.64)			
Change at Week 76 from Period 1 Baseline (n=85)	-4.91 (± 2.50)			
Change at Week 76 from Period 2 Baseline (n=85)	1.01 (± 1.42)			
Change at Week 76 from Period 3 Baseline (n=85)	-4.75 (± 2.49)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Subject Assessment of Disease Activity (SADA) Visual Analogue Scale (VAS): Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in Subject Assessment of Disease Activity (SADA) Visual Analogue Scale (VAS): Last Observation Carried Forward (LOCF): Period 1

End point description:

Subjects assessed their overall disease activity over the last 48 hours by using a 100 mm pain scale that ranges from 0 mm (none) to 100 mm (severe pain), where higher scores indicated more pain. The reported values then converted to cm for analysis purposes. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: cm				
arithmetic mean (standard deviation)				
Baseline (n=209)	6.34 (± 2.14)			
Change at week 4 (n=208)	-2.48 (± 2.45)			
Change at week 8 (n=208)	-3.04 (± 2.69)			
Change at week 12 (n=208)	-3.35 (± 2.74)			
Change at week 16 (n=208)	-3.70 (± 2.80)			
Change at week 24 (n=208)	-4.45 (± 2.87)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Subject Assessment of Disease Activity (SADA) Visual Analogue Scale (VAS): Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in Subject Assessment of Disease Activity (SADA) Visual Analogue Scale (VAS): Last Observation Carried Forward (LOCF): Period 2

End point description:

Subjects assessed their overall disease activity over the last 48 hours by using a 100 mm pain scale that ranges from 0 mm (none) to 100 mm (severe pain), where higher scores indicated more pain. The reported values then converted to cm for analysis purposes. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: cm				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.61 (± 0.57)			
Change at Week 28 from Period 1 Baseline (n=112)	-4.08 (± 3.01)			
Change at Week 28 from Period 2 Baseline (n=112)	1.46 (± 2.47)			
Change at Week 32 from Period 1 Baseline (n=115)	-3.24 (± 3.33)			
Change at Week 32 from Period 2 Baseline (n=115)	2.27 (± 2.81)			
Change at Week 40 from Period 1 Baseline (n=115)	-2.73 (± 3.29)			
Change at Week 40 from Period 2 Baseline (n=115)	2.79 (± 2.92)			
Change at Week 48 from Period 1 Baseline (n=115)	-2.33 (± 3.22)			
Change at Week 48 from Period 2 Baseline (n=115)	3.18 (± 2.99)			
Change at Week 56 from Period 1 Baseline (n=115)	-2.09 (± 3.13)			
Change at Week 56 from Period 2 Baseline (n=115)	3.42 (± 3.00)			
Change at Week 64 from Period 1 Baseline (n=115)	-1.81 (± 3.10)			
Change at Week 64 from Period 2 Baseline (n=115)	3.71 (± 3.04)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Subject Assessment of Disease Activity (SADA) Visual Analogue Scale (VAS): Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in Subject Assessment of Disease Activity (SADA) Visual Analogue Scale (VAS): Last Observation Carried Forward (LOCF): Period 3

End point description:

Subjects assessed their overall disease activity over the last 48 hours by using a 100 mm pain scale that ranges from 0 mm (none) to 100 mm (severe pain), where higher scores indicated more pain. The reported values then converted to cm for analysis purposes. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: cm				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=87)	6.27 (± 2.24)			
Change at Week 64 from Period 1 Baseline (n=15)	-0.26 (± 4.09)			
Change at Week 64 from Period 2 Baseline(n=15)	4.95 (± 2.35)			
Change at Week 64 from Period 3 Baseline (n=15)	0.67 (± 2.48)			
Change at Week 68 from Period 1 Baseline (n=86)	-4.17 (± 2.66)			
Change at Week 68 from Period 2 Baseline (n=86)	1.66 (± 1.91)			
Change at Week 68 from Period 3 Baseline (n=86)	-4.03 (± 2.66)			
Change at Week 72 from Period 1 Baseline (n=87)	-4.60 (± 2.59)			
Change at Week 72 from Period 2 Baseline(n=87)	1.23 (± 1.87)			
Change at Week 72 from Period 3 Baseline (n=86)	-4.44 (± 2.64)			
Change at Week 76 from Period 1 Baseline (n=87)	-4.83 (± 2.54)			
Change at Week 76 from Period 2 Baseline (n=87)	1.01 (± 1.43)			
Change at Week 76 from Period 3 Baseline (n=87)	-4.66 (± 2.52)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Physician Global Assessment (PGA) Visual Analogue Scale (VAS): Observed Cases (OC): Period 1

End point title	Change From Baseline in Physician Global Assessment (PGA) Visual Analogue Scale (VAS): Observed Cases (OC): Period 1

End point description:

The physician assessed the overall disease activity of subjects over the last 48 hours by using a 100 mm VAS pain scale that ranges from 0 mm (none) to 100 mm (severe pain), where higher scores indicated more pain. The reported values then converted to cm for analysis purposes. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	208			
Units: cm				
arithmetic mean (standard deviation)				
Baseline (n=208)	6.07 (± 1.88)			
Change at week 4 (n=207)	-2.89 (± 2.41)			
Change at week 8 (n=200)	-3.83 (± 2.52)			
Change at week 12 (n=196)	-4.16 (± 2.41)			
Change at week 16 (n=191)	-4.57 (± 2.39)			
Change at week 24 (n=189)	-4.81 (± 2.26)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Physician Global Assessment (PGA) Visual Analogue Scale (VAS): Observed Cases (OC): Period 2

End point title	Change From Baseline in Physician Global Assessment (PGA) Visual Analogue Scale (VAS): Observed Cases (OC): Period 2

End point description:

The physician assessed the overall disease activity of subjects over the last 48 hours by using a 100 mm VAS pain scale that ranges from 0 mm (none) to 100 mm (severe pain), where higher scores indicated more pain. The reported values then converted to cm for analysis purposes. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: cm				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.63 (± 0.82)			
Change at Week 28 from Period 1 Baseline (n=109)	-4.65 (± 2.50)			
Change at Week 28 from Period 2 Baseline (n=110)	0.92 (± 1.69)			
Change at Week 32 from Period 1 Baseline (n=93)	-4.27 (± 2.61)			
Change at Week 32 from Period 2 Baseline(n=93)	1.33 (± 1.92)			
Change at Week 40 from Period 1 Baseline (n=69)	-3.98 (± 3.22)			
Change at Week 40 from Period 2 Baseline(n=69)	1.59 (± 2.07)			

Change at Week 48 from Period 1 Baseline (n=53)	-4.78 (± 2.45)			
Change at Week 48 from Period 2 Baseline (n=53)	1.24 (± 1.97)			
Change at Week 56 from Period 1 Baseline (n=42)	-4.67 (± 2.45)			
Change at Week 56 from Period 2 Baseline(n=42)	1.16 (± 1.79)			
Change at Week 64 from Period 1 Baseline (n=34)	-4.22 (± 2.63)			
Change at Week 64 from Period 2 Baseline (n=34)	1.40 (± 2.42)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Physician Global Assessment (PGA) Visual Analogue Scale (VAS): Observed Cases (OC): Period 3

End point title	Change From Baseline in Physician Global Assessment (PGA) Visual Analogue Scale (VAS): Observed Cases (OC): Period 3

End point description:

The physician assessed the overall disease activity of subjects over the last 48 hours by using a 100 mm VAS pain scale that ranges from 0 mm (none) to 100 mm (severe pain), where higher scores indicated more pain. The reported values then converted to cm for analysis purposes. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: cm				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=85)	4.89 (± 1.99)			
Change at Week 64 from Period 1 Baseline (n=14)	-2.18 (± 2.91)			
Change at Week 64 from Period 2 Baseline (n=15)	4.52 (± 1.85)			
Change at Week 64 from Period 3 Baseline (n=13)	1.88 (± 2.21)			
Change at Week 68 from Period 1 Baseline (n=84)	-4.51 (± 2.15)			
Change at Week 68 from Period 2 Baseline (n=85)	1.06 (± 1.31)			
Change at Week 68 from Period 3 Baseline(n=83)	-3.17 (± 2.09)			
Change at Week 72 from Period 1 Baseline (n=86)	-4.89 (± 1.92)			

Change at Week 72 from Period 2 Baseline (n=87)	0.70 (± 1.09)			
Change at Week 72 from Period 3 Baseline (n=85)	-3.52 (± 2.25)			
Change at Week 76 from Period 1 Baseline (n=86)	-5.25 (± 1.98)			
Change at Week 76 from Period 2 Baseline (n=87)	0.34 (± 0.83)			
Change at Week 76 from Period 3 Baseline (n=85)	-3.95 (± 2.22)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Physician Global Assessment (PGA) Visual Analogue Scale (VAS): Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in Physician Global Assessment (PGA) Visual Analogue Scale (VAS): Last Observation Carried Forward (LOCF): Period 1

End point description:

The physician assessed the overall disease activity of subjects over the last 48 hours by using a 100 mm VAS pain scale that ranges from 0 mm (none) to 100 mm (severe pain), where higher scores indicated more pain. The reported values then converted to cm for analysis purposes. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 4, 8, 12, 16, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	208			
Units: cm				
arithmetic mean (standard deviation)				
Baseline (n=208)	6.07 (± 1.88)			
Change at week 4 (n=207)	-2.89 (± 2.41)			
Change at week 8 (n=207)	-3.76 (± 2.61)			
Change at week 12(n=207)	-4.02 (± 2.56)			
Change at week 16(n=207)	-4.32 (± 2.58)			
Change at week 24(n=207)	-4.54 (± 2.51)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Physician Global Assessment (PGA) Visual

Analogue Scale (VAS): Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in Physician Global Assessment (PGA) Visual Analogue Scale (VAS): Last Observation Carried Forward (LOCF): Period 2

End point description:

The physician assessed the overall disease activity of subjects over the last 48 hours by using a 100 mm VAS pain scale that ranges from 0 mm (none) to 100 mm (severe pain), where higher scores indicated more pain. The reported values then converted to cm for analysis purposes. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 28, 32, 40, 48, 56, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: cm				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.63 (± 0.82)			
Change at Week 28 from Period 1 Baseline (n=109)	-4.65 (± 2.50)			
Change at Week 28 from Period 2 Baseline (n=110)	0.92 (± 1.69)			
Change at Week 32 from Period 1 Baseline (n=112)	-3.91 (± 2.69)			
Change at Week 32 from Period 2 Baseline (n=113)	1.64 (± 2.11)			
Change at Week 40 from Period 1 Baseline (n=112)	-3.31 (± 3.04)			
Change at Week 40 from Period 2 Baseline(n=113)	2.24 (± 2.31)			
Change at Week 48 from Period 1 Baseline (n=112)	-3.15 (± 3.00)			
Change at Week 48 from Period 2 Baseline(n=113)	2.40 (± 2.43)			
Change at Week 56 from Period 1 Baseline (n=112)	-2.89 (± 2.93)			
Change at Week 56 from Period 2 Baseline (n=113)	2.65 (± 2.40)			
Change at Week 64 from Period 1 Baseline (n=112)	-2.66 (± 2.88)			
Change at Week 64 from Period 2 Baseline (n=113)	2.88 (± 2.53)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Physician Global Assessment (PGA) Visual Analogue Scale (VAS): Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in Physician Global Assessment (PGA) Visual Analogue Scale (VAS): Last Observation Carried Forward (LOCF): Period 3

End point description:

The physician assessed the overall disease activity of subjects over the last 48 hours by using a 100 mm VAS pain scale that ranges from 0 mm (none) to 100 mm (severe pain), where higher scores indicated more pain. The reported values then converted to cm for analysis purposes. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 68, 72, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: cm				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=85)	4.89 (± 1.99)			
Change at Week 64 from Period 1 Baseline (n=14)	-2.18 (± 2.91)			
Change at Week 64 from Period 2 Baseline (n=15)	4.52 (± 1.85)			
Change at Week 64 from Period 3 Baseline (n=13)	1.88 (± 2.21)			
Change at Week 68 from Period 1 Baseline (n=85)	-4.46 (± 2.19)			
Change at Week 68 from Period 2 Baseline (n=86)	1.12 (± 1.42)			
Change at Week 68 from Period 3 Baseline (n=84)	-3.10 (± 2.18)			
Change at Week 72 from Period 1 Baseline (n=86)	-4.89 (± 1.92)			
Change at Week 72 from Period 2 Baseline (n=87)	0.70 (± 1.09)			
Change at Week 72 from Period 3 Baseline (n=85)	-3.52 (± 2.25)			
Change at Week 76 from Period 1 Baseline (n=86)	-5.22 (± 1.99)			
Change at Week 76 from Period 2 Baseline (n=87)	0.37 (± 0.89)			
Change at Week 76 from Period 3 Baseline (n=85)	-3.85 (± 2.27)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Bath Ankylosing Spondylitis Global Index (BAS-G) Score at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in Bath Ankylosing Spondylitis Global Index (BAS-G) Score at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point description:

The BAS-G was a 2-question assessment evaluating the effect of AS on the subject's wellbeing over the last week and last 6 months. Each question scored by the subject on a 100 mm VAS scale ranging from 0 (very Good) to 100 (very Bad), where higher scores indicated worse health condition. The total BAS-G score calculated as the average scores of these two questions and then converted into cm for analysis. Total BAS-G score ranged from 0 to 10 cm, where higher scores indicated worse health condition. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: cm				
arithmetic mean (standard deviation)				
Baseline (n=209)	6.48 (± 1.93)			
Change at week 12 (n=207)	-2.58 (± 2.25)			
Change at week 24 (n=207)	-3.95 (± 2.64)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Bath Ankylosing Spondylitis Global Index (BAS-G) Score) at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in Bath Ankylosing Spondylitis Global Index (BAS-G) Score) at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point description:

The BAS-G was a 2-question assessment evaluating the effect of AS on the subject's wellbeing over the last week and last 6 months. Each question scored by the subject on a 100 mm VAS scale ranging from 0 (very Good) to 100 (very Bad), where higher scores indicated worse health condition. The total BAS-G score calculated as the average scores of these two questions and then converted into cm for analysis. Total BAS-G score ranged from 0 to 10 cm, where higher scores indicated worse health condition. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: cm				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	1.39 (± 1.49)			
Change at Week 32 from Period 1 Baseline (n=107)	-3.78 (± 2.79)			
Change at Week 32 from Period 2 Baseline (n=107)	1.10 (± 2.22)			
Change at Week 48 from Period 1 Baseline (n=108)	-3.04 (± 2.80)			
Change at Week 48 from Period 2 Baseline (n=108)	1.84 (± 2.46)			
Change at Week 64 from Period 1 Baseline (n=108)	-2.64 (± 2.72)			
Change at Week 64 from Period 2 Baseline (n=108)	2.24 (± 2.58)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Bath Ankylosing Spondylitis Global Index (BAS-G) Score at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in Bath Ankylosing Spondylitis Global Index (BAS-G) Score at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point description:

The BAS-G was a 2-question assessment evaluating the effect of AS on the subject's wellbeing over the last week and last 6 months. Each question scored by the subject on a 100 mm VAS scale ranging from 0 (very Good) to 100 (very Bad), where higher scores indicated worse health condition. The total BAS-G score calculated as the average scores of these two questions and then converted into cm for analysis. Total BAS-G score ranged from 0 to 10 cm, where higher scores indicated worse health condition. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: cm				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=80)	4.74 (± 2.02)			
Change at Week 64 from Period 1 Baseline (n=15)	-2.23 (± 2.41)			

Change at Week 64 from Period 2 Baseline (n=15)	2.94 (± 1.81)			
Change at Week 64 from Period 3 Baseline (n=8)	0.83 (± 2.16)			
Change at Week 76 from Period 1 Baseline (n=86)	-4.35 (± 2.46)			
Change at Week 76 from Period 2 Baseline (n=86)	0.57 (± 1.74)			
Change at Week 76 from Period 3 Baseline (n=80)	-2.53 (± 2.10)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Bath Ankylosing Spondylitis Global Index (BAS-G) Score at Week 12, 24: Observed Cases (OC): Period 1

End point title	Change From Baseline in Bath Ankylosing Spondylitis Global Index (BAS-G) Score at Week 12, 24: Observed Cases (OC): Period 1

End point description:

The BAS-G was a 2-question assessment evaluating the effect of AS on the subject's wellbeing over the last week and last 6 months. Each question scored by the subject on a 100 mm VAS scale ranging from 0 (very Good) to 100 (very Bad), where higher scores indicated worse health condition. The total BAS-G score calculated as the average scores of these two questions and then converted into cm for analysis. Total BAS-G score ranged from 0 to 10 cm, where higher scores indicated worse health condition. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: cm				
arithmetic mean (standard deviation)				
Baseline (n=209)	6.48 (± 1.93)			
Change at week 12 (n=207)	-2.58 (± 2.25)			
Change at week 24 (n=191)	-4.11 (± 2.62)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Bath Ankylosing Spondylitis Global Index (BAS-G) Score) at Week 32, 48, 64: Observed Cases (OC): Period 2

End point title	Change From Baseline in Bath Ankylosing Spondylitis Global

	Index (BAS-G) Score) at Week 32, 48, 64: Observed Cases (OC): Period 2

End point description:

The BAS-G was a 2-question assessment evaluating the effect of AS on the subject's wellbeing over the last week and last 6 months. Each question scored by the subject on a 100 mm VAS scale ranging from 0 (very Good) to 100 (very Bad), where higher scores indicated worse health condition. The total BAS-G score calculated as the average scores of these two questions and then converted into cm for analysis. Total BAS-G score ranged from 0 to 10 cm, where higher scores indicated worse health condition. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: cm				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	1.39 (± 1.49)			
Change at Week 32 from Period 1 Baseline (n=107)	-3.78 (± 2.79)			
Change at Week 32 from Period 2 Baseline(n=107)	1.10 (± 2.22)			
Change at Week 48 from Period 1 Baseline (n=66)	-3.54 (± 2.51)			
Change at Week 48 from Period 2 Baseline (n=66)	1.44 (± 2.37)			
Change at Week 64 from Period 1 Baseline (n=41)	-3.52 (± 2.51)			
Change at Week 64 from Period 2 Baseline (n=41)	1.58 (± 2.55)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Bath Ankylosing Spondylitis Global Index (BAS-G) Score at Week 64, 76: Observed Cases (OC): Period 3

End point title	Change From Baseline in Bath Ankylosing Spondylitis Global Index (BAS-G) Score at Week 64, 76: Observed Cases (OC): Period 3

End point description:

The BAS-G was a 2-question assessment evaluating the effect of AS on the subject's wellbeing over the last week and last 6 months. Each question scored by the subject on a 100 mm VAS scale ranging from 0 (very Good) to 100 (very Bad), where higher scores indicated worse health condition. The total BAS-G score calculated as the average scores of these two questions and then converted into cm for analysis. Total BAS-G score ranged from 0 to 10 cm, where higher scores indicated worse health condition. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: cm				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=80)	4.74 (± 2.02)			
Change at Week 64 from Period 1 Baseline (n=15)	-2.23 (± 2.41)			
Change at Week 64 from Period 2 Baseline (n=15)	2.94 (± 1.81)			
Change at Week 64 from Period 3 Baseline (n=8)	0.83 (± 2.16)			
Change at Week 76 from Period 1 Baseline (n=86)	-4.35 (± 2.46)			
Change at Week 76 from Period 2 Baseline (n=86)	0.57 (± 1.74)			
Change at Week 76 from Period 3 Baseline (n=80)	-2.53 (± 2.10)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Swollen Joint Count at Week 12, 24: Observed Cases (OC): Period 1

End point title	Change From Baseline in Number of Swollen Joint Count at Week 12, 24: Observed Cases (OC): Period 1

End point description:

Number of swollen joints was determined by examination of 44 joints and identifying when swelling was present. The number of swollen joints was recorded on the joint assessment form at each visit, no swelling =0, swelling =1. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: swollen joints				
arithmetic mean (standard deviation)				
Baseline (n=147)	2.32 (± 3.01)			
Change at week 12 (n=91)	-1.72 (± 3.36)			

Change at week 24 (n=60)	-1.85 (± 3.82)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Swollen Joint Count at Week 32, 48, 64: Observed Cases (OC): Period 2

End point title	Change From Baseline in Number of Swollen Joint Count at Week 32, 48, 64: Observed Cases (OC): Period 2

End point description:

Number of swollen joints was determined by examination of 44 joints and identifying when swelling was present. The number of swollen joints was recorded on the joint assessment form at each visit, no swelling =0, swelling =1. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: swollen joints				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=77)	0.95 (± 1.89)			
Change at Week 32 from Period 1 Baseline (n=26)	-2.69 (± 3.28)			
Change at Week 32 from Period 2 Baseline (n=26)	0.46 (± 1.79)			
Change at Week 48 from Period 1 Baseline (n=22)	-1.64 (± 2.40)			
Change at Week 48 from Period 2 Baseline (n=22)	-0.59 (± 2.20)			
Change at Week 64 from Period 1 Baseline (n=11)	-0.82 (± 2.27)			
Change at Week 64 from Period 2 Baseline (n=11)	0.36 (± 2.62)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Swollen Joint Count at Week 64, 76: Observed Cases (OC): Period 3

End point title	Change From Baseline in Number of Swollen Joint Count at Week 64, 76: Observed Cases (OC): Period 3

End point description:

Number of swollen joints was determined by examination of 44 joints and identifying when swelling was present. The number of swollen joints was recorded on the joint assessment form at each visit, no swelling =0, swelling =1. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: swollen joints				
arithmetic mean (standard deviation)				
Period 3: baseline (n=42)	1.19 (± 1.76)			
Change at Week 64 from Period 1 Baseline (n=6)	-0.67 (± 1.03)			
Change at Week 64 from Period 2 Baseline (n=6)	1.17 (± 2.48)			
Change at Week 64 from Period 3 Baseline (n=3)	0.33 (± 1.53)			
Change at Week 76 from Period 1 Baseline (n=18)	-2.50 (± 3.13)			
Change at Week 76 from Period 2 Baseline (n=18)	0.50 (± 1.34)			
Change at Week 76 from Period 3 Baseline (n=17)	-0.88 (± 1.96)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Swollen Joint Count at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in Number of Swollen Joint Count at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point description:

Number of swollen joints was determined by examination of 44 joints and identifying when swelling was present. The number of swollen joints was recorded on the joint assessment form at each visit, no swelling =0, swelling =1. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: swollen joints				
arithmetic mean (standard deviation)				
Baseline (n=147)	2.32 (± 3.01)			
Change at week 12 (n=91)	-1.72 (± 3.36)			
Change at week 24 (n=96)	-1.92 (± 3.52)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Swollen Joint Count at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in Number of Swollen Joint Count at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point description:

Number of swollen joints was determined by examination of 44 joints and identifying when swelling was present. The number of swollen joints was recorded on the joint assessment form at each visit, no swelling =0, swelling =1. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: swollen joints				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=77)	0.95 (± 1.89)			
Change at Week 32 from Period 1 Baseline (n=26)	-2.69 (± 3.28)			
Change at Week 32 from Period 2 Baseline (n=26)	0.46 (± 1.79)			
Change at Week 48 from Period 1 Baseline (n=42)	-2.24 (± 3.00)			
Change at Week 48 from Period 2 Baseline (n=42)	-0.02 (± 2.17)			
Change at Week 64 from Period 1 Baseline (n=47)	-2.00 (± 3.05)			

Change at Week 64 from Period 2 Baseline (n=47)	0.04 (± 2.37)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Swollen Joint Count at Week 64, 76 : Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in Number of Swollen Joint Count at Week 64, 76 : Last Observation Carried Forward (LOCF): Period 3

End point description:

Number of swollen joints was determined by examination of 44 joints and identifying when swelling was present. The number of swollen joints was recorded on the joint assessment form at each visit, no swelling =0, swelling =1. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: swollen joints				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=42)	1.19 (± 1.76)			
Change at Week 64 from Period 1 Baseline (n=6)	-0.67 (± 1.03)			
Change at Week 64 from Period 2 Baseline (n=6)	1.17 (± 2.48)			
Change at Week 64 from Period 3 Baseline (n=3)	0.33 (± 1.53)			
Change at Week 76 from Period 1 Baseline (n=19)	-2.32 (± 3.15)			
Change at Week 76 from Period 2 Baseline (n=19)	0.53 (± 1.31)			
Change at Week 76 from Period 3 Baseline (n=18)	-0.72 (± 2.02)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Tender Joint Count at Week 12, 24:

Observed Cases (OC): Period 1

End point title	Change From Baseline in Number of Tender Joint Count at Week 12, 24: Observed Cases (OC): Period 1

End point description:

Number of tender joints was determined by examining 44 joints and identified the joints that were painful under pressure or to passive motion. The number of tender joints was recorded on the joint assessment form at each visit, no tenderness = 0, tenderness = 1. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	147			
Units: tender joints				
arithmetic mean (standard deviation)				
Baseline (n=147)	5.96 (± 5.44)			
Change at week 12 (n=91)	-2.82 (± 4.86)			
Change at week 24 (n=24)	-3.67 (± 5.72)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Tender Joint Count at Week 32, 48, 64: Observed Cases (OC): Period 2

End point title	Change From Baseline in Number of Tender Joint Count at Week 32, 48, 64: Observed Cases (OC): Period 2

End point description:

Number of tender joints was determined by examining 44 joints and identified the joints that were painful under pressure or to passive motion. The number of tender joints was recorded on the joint assessment form at each visit, no tenderness = 0, tenderness = 1. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	77			
Units: tender joints				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=77)	2.70 (± 2.58)			
Change at Week 32 from Period 1 Baseline (n=26)	-3.27 (± 4.65)			
Change at Week 32 from Period 2 Baseline (n=26)	0.61 (± 2.70)			
Change at Week 48 from Period 1 Baseline (n=22)	-2.68 (± 3.71)			
Change at Week 48 from Period 2 Baseline (n=22)	-0.73 (± 3.56)			
Change at Week 64 from Period 1 Baseline (n=11)	-2.27 (± 2.28)			
Change at Week 64 from Period 2 Baseline (n=11)	0.18 (± 3.74)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Tender Joint Count at Week 64, 76: : Observed Cases (OC): Period 3

End point title	Change From Baseline in Number of Tender Joint Count at Week 64, 76: : Observed Cases (OC): Period 3

End point description:

Number of tender joints was determined by examining 44 joints and identified the joints that were painful under pressure or to passive motion. The number of tender joints was recorded on the joint assessment form at each visit, no tenderness = 0, tenderness = 1. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	42			
Units: tender joints				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=42)	3.60 (± 2.80)			
Change at Week 64 from Period 1 Baseline (n=6)	-0.17 (± 1.47)			
Change at Week 64 from Period 2 Baseline (n=6)	0.33 (± 1.97)			
Change at Week 64 from Period 3 Baseline (n=3)	0.00 (± 2.00)			

Change at Week 76 from Period 1 Baseline (n=18)	-3.56 (± 2.91)			
Change at Week 76 from Period 2 Baseline (n=18)	0.06 (± 1.63)			
Change at Week 76 from Period 3 Baseline (n=17)	-1.94 (± 2.41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Tender Joint Count at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in Number of Tender Joint Count at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point description:

Number of tender joints was determined by examining 44 joints and identified the joints that were painful under pressure or to passive motion. The number of tender joints was recorded on the joint assessment form at each visit, no tenderness = 0, tenderness = 1. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	147			
Units: tender joints				
arithmetic mean (standard deviation)				
Baseline (n=147)	5.96 (± 5.44)			
Change at week 12 (n=91)	-2.82 (± 4.86)			
Change at week 24 (n=96)	-3.15 (± 5.26)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Tender Joint Count at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in Number of Tender Joint Count at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point description:

Number of tender joints was determined by examining 44 joints and identified the joints that were painful under pressure or to passive motion. The number of tender joints was recorded on the joint assessment form at each visit, no tenderness = 0, tenderness = 1. Full analysis set for Period 2 included

all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	77			
Units: tender joints				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=77)	2.70 (± 2.58)			
Change at Week 32 from Period 1 Baseline (n=26)	-3.27 (± 4.65)			
Change at Week 32 from Period 2 Baseline (n=26)	0.61 (± 2.70)			
Change at Week 48 from Period 1 Baseline (n=42)	-2.88 (± 4.11)			
Change at Week 48 from Period 2 Baseline (n=42)	-0.05 (± 3.37)			
Change at Week 64 from Period 1 Baseline (n=47)	-2.72 (± 3.81)			
Change at Week 64 from Period 2 Baseline (n=47)	-0.09 (± 3.47)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Tender Joint Count at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in Number of Tender Joint Count at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point description:

Number of tender joints was determined by examining 44 joints and identified the joints that were painful under pressure or to passive motion. The number of tender joints was recorded on the joint assessment form at each visit, no tenderness = 0, tenderness = 1. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	42			
Units: tender joints				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=42)	3.60 (± 2.80)			
Change at Week 64 from Period 1 Baseline (n=6)	-0.17 (± 1.47)			
Change at Week 64 from Period 2 Baseline (n=6)	0.33 (± 1.97)			
Change at Week 64 from Period 3 Baseline (n=3)	0.00 (± 2.00)			
Change at Week 76 from Period 1 Baseline (n=19)	-3.32 (± 3.02)			
Change at Week 76 from Period 2 Baseline(n=19)	0.11 (± 1.59)			
Change at Week 76 from Period 3 Baseline(n=18)	-1.72 (± 2.52)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Dactylitis Total Score at Week 12, 24: Observed Cases (OC): Period 1

End point title	Change From Baseline in Dactylitis Total Score at Week 12, 24: Observed Cases (OC): Period 1

End point description:

Dactylitis is the inflammation of finger and/or toe joints (digits). Dactylitis scores was calculated by evaluating each of the 10 fingers and 10 toes. Each digit was evaluated on a 4-point scale ranging from of 0 to 3 where 0 = none, 1= mild, 2 = moderate, 3 = severe inflammation. The total score was calculated as the sum of scores for the 20 digits, total score ranged from 0 to 60, where higher scores indicated severe inflammation. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=209)	0.42 (± 1.43)			
Change at week 12 (n=207)	-0.27 (± 1.45)			
Change at week 24(n=191)	-0.30 (± 1.44)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Dactylitis Total Score at Week 32, 48, 64: Observed Cases (OC): Period 2

End point title	Change From Baseline in Dactylitis Total Score at Week 32, 48, 64: Observed Cases (OC): Period 2

End point description:

Dactylitis is the inflammation of finger and/or toe joints (digits). Dactylitis scores was calculated by evaluating each of the 10 fingers and 10 toes. Each digit was evaluated on a 4-point scale ranging from of 0 to 3 where 0 = none, 1= mild, 2 = moderate, 3 = severe inflammation. The total score was calculated as the sum of scores for the 20 digits, total score ranged from 0 to 60, where higher scores indicated severe inflammation. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.02 (± 0.13)			
Change at Week 32 from Period 1 Baseline (n=107)	-0.42 (± 1.32)			
Change at Week 32 from Period 2 Baseline (n=107)	0.01 (± 0.22)			
Change at Week 48 from Period 1 Baseline (n=66)	-0.36 (± 1.26)			
Change at Week 48 from Period 2 Baseline (n=66)	0.09 (± 0.74)			
Change at Week 64 from Period 1 Baseline (n=42)	-0.57 (± 1.61)			
Change at Week 64 from Period 2 Baseline(n=42)	0.07 (± 0.34)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Dactylitis Total Score at Week 64, 76: Observed

Cases (OC): Period 3

End point title	Change From Baseline in Dactylitis Total Score at Week 64, 76: Observed Cases (OC): Period 3

End point description:

Dactylitis is the inflammation of finger and/or toe joints (digits). Dactylitis scores was calculated by evaluating each of the 10 fingers and 10 toes. Each digit was evaluated on a 4-point scale ranging from of 0 to 3 where 0 = none, 1= mild, 2 = moderate, 3 = severe inflammation. The total score was calculated as the sum of scores for the 20 digits, total score ranged from 0 to 60, where higher scores indicated severe inflammation. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=80)	0.08 (± 0.35)			
Change at Week 64 from Period 1 Baseline (n=15)	-0.33 (± 1.05)			
Change at Week 64 from Period 2 Baseline(n=15)	0.20 (± 0.56)			
Change at Week 64 from Period 3 Baseline (n=8)	0.25 (± 0.71)			
Change at Week 76 from Period 1 Baseline (n=86)	-0.50 (± 1.47)			
Change at Week 76 from Period 2 Baseline (n=86)	0.00 (± 0.15)			
Change at Week 76 from Period 3 Baseline (n=80)	-0.06 (± 0.37)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Dactylitis Total Score at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in Dactylitis Total Score at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point description:

Dactylitis is the inflammation of finger and/or toe joints (digits). Dactylitis scores was calculated by evaluating each of the 10 fingers and 10 toes. Each digit was evaluated on a 4-point scale ranging from of 0 to 3 where 0 = none, 1= mild, 2 = moderate, 3 = severe inflammation. The total score was calculated as the sum of scores for the 20 digits, total score ranged from 0 to 60, where higher scores indicated severe inflammation. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	209			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=209)	0.42 (± 1.43)			
Change at week 12 (n=207)	-0.27 (± 1.45)			
Change at week 24 (n=207)	-0.28 (± 1.38)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Dactylitis Total Score at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in Dactylitis Total Score at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point description:

Dactylitis is the inflammation of finger and/or toe joints (digits). Dactylitis scores was calculated by evaluating each of the 10 fingers and 10 toes. Each digit was evaluated on a 4-point scale ranging from of 0 to 3 where 0 = none, 1= mild, 2 = moderate, 3 = severe inflammation. The total score was calculated as the sum of scores for the 20 digits, total score ranged from 0 to 60, where higher scores indicated severe inflammation. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.02 (± 0.13)			
Change at Week 32 from Period 1 Baseline (n=107)	-0.42 (± 1.32)			
Change at Week 32 from Period 2 Baseline (n=107)	0.01 (± 0.22)			
Change at Week 48 from Period 1 Baseline (n=108)	-0.36 (± 1.24)			
Change at Week 48 from Period 2 Baseline (n=108)	0.06 (± 0.62)			

Change at Week 64 from Period 1 Baseline (n=108)	-0.39 (± 1.28)			
Change at Week 64 from Period 2 Baseline (n=108)	0.04 (± 0.30)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Dactylitis Total Score at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in Dactylitis Total Score at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point description:

Dactylitis is the inflammation of finger and/or toe joints (digits). Dactylitis scores was calculated by evaluating each of the 10 fingers and 10 toes. Each digit was evaluated on a 4-point scale ranging from of 0 to 3 where 0 = none, 1= mild, 2 = moderate, 3 = severe inflammation. The total score was calculated as the sum of scores for the 20 digits, total score ranged from 0 to 60, where higher scores indicated severe inflammation. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2 Baseline (last visit before treatment withdrawal), Period 3 Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=80)	0.08 (± 0.35)			
Change at Week 64 from Period 1 Baseline (n=15)	-0.33 (± 1.05)			
Change at Week 64 from Period 2 Baseline(n=15)	0.20 (± 0.56)			
Change at Week 64 from Period 3 Baseline (n=8)	0.25 (± 0.71)			
Change at Week 76 from Period 1 Baseline (n=86)	-0.50 (± 1.47)			
Change at Week 76 from Period 2 Baseline (n=86)	0.00 (± 0.15)			
Change at Week 76 from Period 3 Baseline (n=80)	-0.06 (± 0.37)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) at Week 12, 24: Observed Cases (OC) : Period 1

End point title	Change From Baseline in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) at Week 12, 24: Observed Cases (OC) : Period 1

End point description:

The MASES is an index used to measure the severity of enthesitis. Enthesitis is the inflammation of enthuses (heels). The MASES assesses 13 sites for enthesitis. Each site is scored as 0 or 1 depending on whether enthesitis is present or absent. Sites assessed include 1st costochondral joint (left/right), 7 th costochondral joint (l/r), posterior superior iliac spine (l/r), posterior anterior iliac spine (l/r), iliac crest (l/r), proximal insertion of Achilles tendon (l/r) and 5th lumbar spinous process. The MASES is the sum of all site scores range from 0 (no inflammation) to 13 (worst possible inflammation) where higher scores indicate more severe inflammation of entheses. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	208			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=208)	2.86 (± 2.98)			
Change at week 12 (n=205)	-1.22 (± 2.55)			
Change at week 24 (n=190)	-1.59 (± 2.59)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) at Week 32, 48, 64: Observed Cases (OC): Period 2

End point title	Change From Baseline in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) at Week 32, 48, 64: Observed Cases (OC): Period 2

End point description:

The MASES is an index used to measure the severity of enthesitis. Enthesitis is the inflammation of enthuses (heels). The MASES assesses 13 sites for enthesitis. Each site is scored as 0 or 1 depending on whether enthesitis is present or absent. Sites assessed include 1st costochondral joint (left/right), 7 th costochondral joint (l/r), posterior superior iliac spine (l/r), posterior anterior iliac spine (l/r), iliac crest (l/r), proximal insertion of Achilles tendon (l/r) and 5th lumbar spinous process. The MASES is the sum of all site scores range from 0 (no inflammation) to 13 (worst possible inflammation) where higher scores indicate more severe inflammation of entheses. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.36 (± 0.97)			
Change at Week 32 from Period 1 Baseline (n=106)	-1.06 (± 2.49)			
Change at Week 32 from Period 2 Baseline (n=106)	0.71 (± 1.76)			
Change at Week 48 from Period 1 Baseline (n=66)	-1.50 (± 2.48)			
Change at Week 48 from Period 2 Baseline (n=66)	0.32 (± 1.15)			
Change at Week 64 from Period 1 Baseline (n=41)	-1.37 (± 2.30)			
Change at Week 64 from Period 2 Baseline(n=41)	0.49 (± 1.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) at Week 64, 76: Observed Cases (OC): Period 3

End point title	Change From Baseline in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) at Week 64, 76: Observed Cases (OC): Period 3

End point description:

The MASES is an index used to measure the severity of enthesitis. Enthesitis is the inflammation of enthuses (heels). The MASES assesses 13 sites for enthesitis. Each site is scored as 0 or 1 depending on whether enthesitis is present or absent. Sites assessed include 1st costochondral joint (left/right), 7 th costochondral joint (l/r), posterior superior iliac spine (l/r), posterior anterior iliac spine (l/r), iliac crest (l/r), proximal insertion of Achilles tendon (l/r) and 5th lumbar spinous process. The MASES is the sum of all site scores range from 0 (no inflammation) to 13 (worst possible inflammation) where higher scores indicate more severe inflammation of entheses. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Period 3: Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=79)	1.48 (± 1.80)			
Change at Week 64 from Period 1 Baseline (n=15)	-1.13 (± 2.03)			
Change at Week 64 from Period 2 Baseline(n=15)	0.67 (± 2.13)			
Change at Week 64 from Period 3 Baseline (n=7)	0.14 (± 0.90)			
Change at Week 76 from Period 1 Baseline (n=86)	-1.86 (± 2.14)			
Change at Week 76 from Period 2 Baseline(n=86)	-0.06 (± 1.13)			
Change at Week 76 from Period 3 Baseline (n=79)	-1.08 (± 1.61)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point title	Change From Baseline in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) at Week 12, 24: Last Observation Carried Forward (LOCF): Period 1

End point description:

The MASES is an index used to measure the severity of enthesitis. Enthesitis is the inflammation of enthuses (heels). The MASES assesses 13 sites for enthesitis. Each site is scored as 0 or 1 depending on whether enthesitis is present or absent. Sites assessed include 1st costochondral joint (left/right), 7 th costochondral joint (l/r), posterior superior iliac spine (l/r), posterior anterior iliac spine (l/r), iliac crest (l/r), proximal insertion of Achilles tendon (l/r) and 5th lumbar spinous process. The MASES is the sum of all site scores range from 0 (no inflammation) to 13 (worst possible inflammation) where higher scores indicate more severe inflammation of entheses. Full analysis set for Period 1 included all subjects who took study medication and had one evaluation after baseline. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1 Week 1), Week 12, 24

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	208			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=208)	2.86 (± 2.98)			
Change at week 12 (n=205)	-1.22 (± 2.55)			
Change at week 24 (n=206)	-1.55 (± 2.64)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point title	Change From Baseline in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) at Week 32, 48, 64: Last Observation Carried Forward (LOCF): Period 2

End point description:

The MASES is an index used to measure the severity of enthesitis. Enthesitis is the inflammation of enthuses (heels). The MASES assesses 13 sites for enthesitis. Each site is scored as 0 or 1 depending on whether enthesitis is present or absent. Sites assessed include 1st costochondral joint (left/right), 7 th costochondral joint (l/r), posterior superior iliac spine (l/r), posterior anterior iliac spine (l/r), iliac crest (l/r), proximal insertion of Achilles tendon (l/r) and 5th lumbar spinous process. The MASES is the sum of all site scores range from 0 (no inflammation) to 13 (worst possible inflammation) where higher scores indicate more severe inflammation of entheses. Full analysis set for Period 2 included all subjects who had at least one evaluation during period 2. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Week 32, 48, 64

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	115			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 2 Baseline (n=115)	0.36 (± 0.97)			
Change at Week 32 from Period 1 Baseline (n=106)	-1.06 (± 2.49)			
Change at Week 32 from Period 2 Baseline (n=106)	0.71 (± 1.76)			
Change at Week 48 from Period 1 Baseline (n=107)	-1.13 (± 2.47)			
Change at Week 48 from Period 2 Baseline (n=107)	0.62 (± 1.55)			
Change at Week 64 from Period 1 Baseline (n=107)	-1.00 (± 2.24)			
Change at Week 64 from Period 2 Baseline (n=107)	0.75 (± 1.55)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point title	Change From Baseline in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) at Week 64, 76: Last Observation Carried Forward (LOCF): Period 3

End point description:

The MASES is an index used to measure the severity of enthesitis. Enthesitis is the inflammation of enthuses (heels). The MASES assesses 13 sites for enthesitis. Each site is scored as 0 or 1 depending on whether enthesitis is present or absent. Sites assessed include 1st costochondral joint (left/right), 7 th costochondral joint (l/r), posterior superior iliac spine (l/r), posterior anterior iliac spine (l/r), iliac crest (l/r), proximal insertion of Achilles tendon (l/r) and 5th lumbar spinous process. The MASES is the sum of all site scores range from 0 (no inflammation) to 13 (worst possible inflammation) where higher scores indicate more severe inflammation of entheses. Full analysis set for Period 3 included all subjects who took study retreatment medication and had at least one evaluation after restarting active therapy. Missing data was imputed using mixed LOCF. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Period 1 Baseline (Day 1 Week 1), Period 2: Baseline (last visit before treatment withdrawal), Period 3: Baseline (last visit before retreatment), Week 64, 76

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: units on a scale				
arithmetic mean (standard deviation)				
Period 3 Baseline (n=79)	1.48 (± 1.80)			
Change at Week 64 from Period 1 Baseline (n=15)	-1.13 (± 2.03)			
Change at Week 64 from Period 2 Baseline(n=15)	0.67 (± 2.13)			
Change at Week 64 from Period 3 Baseline (n=7)	0.14 (± 0.90)			
Change at Week 76 from Period 1 Baseline (n=86)	-1.86 (± 2.14)			
Change at Week 76 from Period 2 Baseline (n=86)	-0.06 (± 1.13)			
Change at Week 76 from Period 3 Baseline (n=79)	-1.08 (± 1.61)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point title	Number of Subjects With Treatment Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point description:

An AE was any untoward medical occurrence in a subject who received investigational product without regard to possibility of causal relationship. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly; medically important events. Treatment-emergent were events between first dose of investigational product and up to 28 days after the last dose of investigational product that were absent before treatment or that worsened relative to pretreatment state.

End point type	Secondary

End point timeframe:

Baseline (Day 1) up to 28 days after last dose of study drug (for period 1: maximum up to 28 weeks, for period 2: maximum up to 68 weeks, period 3: maximum up to 80 weeks)

End point values	Etanercept: Period 1	Etanercept: Period 2	Etanercept: Period 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	209	119	87	
Units: subjects				
AEs	147	37	29	
SAEs	6	1	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline (Day 1) up to 28 days after last dose of study drug (for period 1: maximum up to 28 weeks, for period 2: maximum up to 68 weeks, period 3: maximum up to 80 weeks)

Adverse event reporting additional description:

Same event may appear as AE and SAE, what is presented are distinct events. Event may be categorized as serious in 1 subject and as non-serious in another subject or 1 subject may have experienced both serious and non-serious event during study.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	Etanercept: Period 1

Reporting group description:

All enrolled subjects with nr-ax SpA were treated for 24 weeks with 50 milligram weekly dose of Etanercept in Period 1 (Induction Period). Subjects who did not qualify for Period 2 were followed up until 28 days after last dose of Etanercept.

Reporting group title	Etanercept: Period 3

Reporting group description:

Subjects who achieved an ASDAS ESR level >= 2.1 by Week 64, then entered into Period 3 (Retreatment Period) of 12 weeks, treated with 50 mg weekly doses, and then followed up until 28 days after last dose of Etanercept.

Reporting group title	Etanercept: Period 2

Reporting group description:

Subjects who achieved ASDAS CRP less than 1.3 at Week 24 then entered into Period 2 (Withdrawal Period). In this period, subjects discontinued Etanercept for 40 weeks (from Week 24 to Week 64). Subjects who did not qualify for Period 2 were followed up until 28 days after last dose of Etanercept.

Serious adverse events	Etanercept: Period 1	Etanercept: Period 3	Etanercept: Period 2
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 209 (2.87%)	0 / 87 (0.00%)	1 / 119 (0.84%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Intraductal proliferative breast lesion			
subjects affected / exposed	1 / 209 (0.48%)	0 / 87 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Limb injury			

subjects affected / exposed	1 / 209 (0.48%)	0 / 87 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	0 / 209 (0.00%)	0 / 87 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral infarction			
subjects affected / exposed	1 / 209 (0.48%)	0 / 87 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 209 (0.48%)	0 / 87 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Uterovaginal prolapse			
subjects affected / exposed	1 / 209 (0.48%)	0 / 87 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	1 / 209 (0.48%)	0 / 87 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Etanercept: Period 1	Etanercept: Period 3	Etanercept: Period 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	72 / 209 (34.45%)	8 / 87 (9.20%)	0 / 119 (0.00%)
General disorders and administration site conditions			

Injection site erythema			
subjects affected / exposed	15 / 209 (7.18%)	0 / 87 (0.00%)	0 / 119 (0.00%)
occurrences (all)	36	0	0
Injection site reaction			
subjects affected / exposed	15 / 209 (7.18%)	0 / 87 (0.00%)	0 / 119 (0.00%)
occurrences (all)	64	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	19 / 209 (9.09%)	2 / 87 (2.30%)	0 / 119 (0.00%)
occurrences (all)	20	13	0
Viral upper respiratory tract infection			
subjects affected / exposed	33 / 209 (15.79%)	8 / 87 (9.20%)	0 / 119 (0.00%)
occurrences (all)	48	10	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported