Clinical trial results:
An Open-Label Extension Study to Assess The Long-Term Safety And Clinical Benefit of Etanercept in Children And Adolescents With Extended Oligoarticular Juvenile Idiopathic Arthritis, Enthesitis-Related Arthritis, or Psoriatic Arthritis Who Were Previously Enrolled in Protocol 0881A1-3338-WW (B1801014)

Summary

EudraCT number	2010-023802-10
Trial protocol	HU BE FR LT SK CZ SI ES DE LV PL NL Outside EU/EEA NO IT
Global end of trial date	04 February 2021

Results information

Result version number	v1 (current)
This version publication date	15 August 2021
First version publication date	15 August 2021

Trial information

Trial identification

Sponsor protocol code	B1801023

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01421069
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)	Yes
EMA paediatric investigation plan number(s)	EMEA-001236-PIP20-10
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	02 March 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 February 2021
Global end of trial reached?	Yes
Global end of trial date	04 February 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To monitor the occurrence of malignancy in pediatric subjects with extended oligoarticular Juvenile idiopathic arthritis (JIA), enthesitis related arthritis (ERA), or psoriatic arthritis (PsA).

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	10 October 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 4
Country: Number of subjects enrolled	Colombia: 3
Country: Number of subjects enrolled	Mexico: 2
Country: Number of subjects enrolled	Russian Federation: 11
Country: Number of subjects enrolled	Serbia: 14
Country: Number of subjects enrolled	Belgium: 10
Country: Number of subjects enrolled	France: 7
Country: Number of subjects enrolled	Germany: 16
Country: Number of subjects enrolled	Hungary: 10
Country: Number of subjects enrolled	Italy: 3
Country: Number of subjects enrolled	Latvia: 9
Country: Number of subjects enrolled	Lithuania: 7
Country: Number of subjects enrolled	Netherlands: 3
Country: Number of subjects enrolled	Norway: 1
Country: Number of subjects enrolled	Poland: 15
Country: Number of subjects enrolled	Slovakia: 2
Country: Number of subjects enrolled	Slovenia: 2
Country: Number of subjects enrolled	Spain: 3
Country: Number of subjects enrolled	Czechia: 5

Worldwide total number of subjects	127
EEA total number of subjects	93

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)	38
Adolescents (12-17 years)	89
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This was an extension study in pediatric subjects diagnosed with one of three subtypes of juvenile idiopathic arthritis (JIA): extended oligoarticular JIA, enthesitis related arthritis (ERA), or psoriatic arthritis (PsA) had received at least one dose of Etanercept and completed approximately 96 weeks of participation in study 0881A1-3338.

Pre-assignment

Screening details:

This study has 3 periods: Active treatment period, Withdrawal/Re-treatment period and Observational period.

Period 1

Period 1 title	Parent Study
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Etanercept

Arm description:

Subjects aged <18 years & weighed <=62 kg received Etanercept(Etn)SC dose of 0.8 mg/kg once a week, for active treatment period (ACT) for maximum of 96 months. Subjects who either met Wallace definition for clinically inactive disease for at least 6 months on Etn or who had a good clinical response & would benefit from withdrawal from Etn & were otherwise eligible entered withdrawal period. Subjects requiring re-treatment per investigator's clinical judgment and otherwise eligible entered re-treatment period. Subjects who discontinued Etn prior to completing 96 weeks of active treatment in study 0881A1-3338 for any reason or not eligible to continue Etn in study B1801023 asked to enter observational period directly. Subjects from ACT,withdrawal/re-treatment period who discontinued Etn prior to completion of study, asked to participate in observational period. In observational period, all subjects followed up for a maximum of 96 months from the time of initial entry into this study.

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:

Etanercept was administered 0.8 mg/kg up to a maximum dose of 50 mg once weekly SC for 96 months.

Number of subjects in period 1	Etanercept
Started	127
Completed	127

Period 2

Period 2 title	Overall study(Extension Study-96 months)
Is this the baseline period?	Yes[1]
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Etanercept

Arm description:

Subjects aged <18 years & weighed <=62 kg received Etanercept(Etn)SC dose of 0.8 mg/kg once a week, for active treatment period (ACT) for maximum of 96 months. Subjects who either met Wallace definition for clinically inactive disease for at least 6 months on Etn or who had a good clinical response & would benefit from withdrawal from Etn & were otherwise eligible entered withdrawal period. Subjects requiring re-treatment per investigator's clinical judgment and otherwise eligible entered re-treatment period. Subjects who discontinued Etn prior to completing 96 weeks of active treatment in study 0881A1-3338 for any reason or not eligible to continue Etn in study B1801023 asked to enter observational period directly. Subjects from ACT,withdrawal/re-treatment period who discontinued Etn prior to completion of study, asked to participate in observational period. In observational period, all subjects followed up for a maximum of 96 months from the time of initial entry into this study.

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:

Etanercept was administered 0.8 mg/kg up to a maximum dose of 50 mg once weekly SC for 96 months.

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Period 1 has the data from the parent study. However, Overall study represents the participant flow for the extension study. Therefore, Overall study (Extension Study-96 months) has been selected as the baseline period.

Number of subjects in period 2[2][3]	Etanercept
Started	109
Entered Active Treatment Period	99
Completed	27
Not completed	82
Medication Error Without Associated Adverse Event	1
Enrolled in Observational Period	29
Adverse event	1
Enrolled in Withdrawal Period	30
Insufficient Clinical Response	1
No Longer Willing To Participate In Study	8
Unspecified	1

Subjects entered in observational period	10
Withdrawn Due To Pregnancy	1

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: The worldwide number represents the subjects enrolled in the parent study. The results reported here are for extension study. Therefore, Overall study (Extension Study-96 months) has been selected as the baseline period and its is not same as worldwide number enrolled in the trial
[3] - 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: The Parent Study period, has the data of subjects form the parent study B1801014. The subjects in the extension study entered from the parent study, mentioned here as Overall study (Extension Study-96 months). So the number of subjects are not same.

Period 3

Period 3 title	Withdrawal(Wit)/Retreatment:Witphase
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Etanercept

Arm description:

Subjects aged <18 years & weighed <=62 kg received Etanercept (Etn) SC dose of 0.8 mg/kg once a week, for ACT for maximum of 96 months. Subjects who either met Wallace definition for clinically inactive disease for at least 6 months on Etn or who had a good clinical response & would benefit from withdrawal from Etn & were otherwise eligible entered withdrawal period. Subjects requiring re-treatment per investigator's clinical judgment and otherwise eligible entered re-treatment period. Subjects who discontinued Etn prior to completing 96 weeks of active treatment in study 0881A1-3338 for any reason or not eligible to continue Etn in study B1801023 asked to enter observational period directly. Subjects from ACT,withdrawal/re-treatment period who discontinued Etn prior to completion of study, asked to participate in observational period. In observational period, all subjects followed up for a maximum of 96 months from the time of initial entry into this study.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 3[4]	Etanercept
Started	27
Completed	7
Not completed	23
Enrolled in Observational Period	7
Enrolled in Re-Treatment Period	13
No Longer Willing To Participate In Study	2
Lost to follow-up	1
Joined	3

Transferred in from other group/arm	3

Notes:

[4] - The number of subjects transferring in and out of the arms in the period are not the same. It is expected the net number of transfers in and out of the arms in a period, will be zero.
Justification: The net number of transfers in and out of the arms in a period, is not zero as few subjects entered the withdrawal period directly from the parent study and were further transferred in observational period or re-treatment period.

Period 4

Period 4 title	Wit/Retreatment:Reteatmentphase
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Etanercept

Arm description:

Subjects aged <18 years & weighed <=62 kg received Etanercept (Etn) SC dose of 0.8 mg/kg once a week, for ACT for maximum of 96 months. Subjects who either met Wallace definition for clinically inactive disease for at least 6 months on Etn or who had a good clinical response & would benefit from withdrawal from Etn & were otherwise eligible entered withdrawal period. Subjects requiring re-treatment per investigator's clinical judgment and otherwise eligible entered re-treatment period. Subjects who discontinued Etn prior to completing 96 weeks of active treatment in study 0881A1-3338 for any reason or not eligible to continue Etn in study B1801023 asked to enter observational period directly. Subjects from ACT, withdrawal/re-treatment period who discontinued Etn prior to completion of study, asked to participate in observational period. In observational period, all subjects followed up for a maximum of 96 months from the time of initial entry into this study.

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:

Etanercept was administered 0.8 mg/kg up to a maximum dose of 50 mg once weekly SC for 96 months.

Number of subjects in period 4[5]	Etanercept
Started	7
Completed	5
Not completed	8
Protocol deviation	1
Enrolled in Observational Period	7
Joined	6

Transferred in from other group/arm	6

Notes:

[5] - The number of subjects transferring in and out of the arms in the period are not the same. It is expected the net number of transfers in and out of the arms in a period, will be zero.
Justification: The net number of transfers in and out of the arms in a period, is not zero as few subjects entered the withdrawal period directly from the parent study and were further transferred in observational period or re-treatment period.

Period 5

Period 5 title	Observational Period (96 months)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Etanercept

Arm description:

Subjects aged <18 years & weighed <=62 kg received Etanercept (Etn) SC dose of 0.8 mg/kg once a week, for ACT for maximum of 96 months. Subjects who either met Wallace definition for clinically inactive disease for at least 6 months on Etn or who had a good clinical response & would benefit from withdrawal from Etn & were otherwise eligible entered withdrawal period. Subjects requiring re-treatment per investigator's clinical judgment and otherwise eligible entered re-treatment period. Subjects who discontinued Etn prior to completing 96 weeks of active treatment in study 0881A1-3338 for any reason or not eligible to continue Etn in study B1801023 asked to enter observational period directly. Subjects from ACT, withdrawal/re-treatment period who discontinued Etn prior to completion of study, asked to participate in observational period. In observational period, all subjects followed up for a maximum of 96 months from the time of initial entry into this study.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 5[6]	Etanercept
Started	5
Completed	45
Not completed	8
Unspecified	1
No Longer Willing To Participate In Study	4
Lost to follow-up	3
Joined	48
Transferred in from other group/arm	48

Notes:

[6] - The number of subjects transferring in and out of the arms in the period are not the same. It is expected the net number of transfers in and out of the arms in a period, will be zero.
Justification: The net number of transfers in and out of the arms in a period, is not zero as few subjects entered the withdrawal period directly from the parent study and were further transferred in observational period or re-treatment period.

Baseline characteristics

Reporting groups	
Reporting group title	Etanercept

Reporting group description:

Subjects aged <18 years & weighed <=62 kg received Etanercept(Etn)SC dose of 0.8 mg/kg once a week, for active treatment period (ACT) for maximum of 96 months. Subjects who either met Wallace definition for clinically inactive disease for at least 6 months on Etn or who had a good clinical response & would benefit from withdrawal from Etn & were otherwise eligible entered withdrawal period. Subjects requiring re-treatment per investigator's clinical judgment and otherwise eligible entered re-treatment period. Subjects who discontinued Etn prior to completing 96 weeks of active treatment in study 0881A1-3338 for any reason or not eligible to continue Etn in study B1801023 asked to enter observational period directly. Subjects from ACT,withdrawal/re-treatment period who discontinued Etn prior to completion of study, asked to participate in observational period. In observational period, all subjects followed up for a maximum of 96 months from the time of initial entry into this study.

Reporting group values	Etanercept	Total	
Number of subjects	109	109	
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)	32	32	
Adolescents (12-17 years)	58	58	
Adults (18-64 years)	19	19	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous Units: years			
arithmetic mean	13.28		
standard deviation	± 4.49	-	
Gender Categorical Units: Subjects			
Female	61	61	
Male	48	48	
Race (NIH/OMB) Units: Subjects			
White	101	101	
Asian	1	1	
Other	7	7	

End points

End points reporting groups

Reporting group title	Etanercept

Reporting group description:

Subjects aged <18 years & weighed <=62 kg received Etanercept(Etn)SC dose of 0.8 mg/kg once a week, for active treatment period (ACT) for maximum of 96 months. Subjects who either met Wallace definition for clinically inactive disease for at least 6 months on Etn or who had a good clinical response & would benefit from withdrawal from Etn & were otherwise eligible entered withdrawal period. Subjects requiring re-treatment per investigator's clinical judgment and otherwise eligible entered re-treatment period. Subjects who discontinued Etn prior to completing 96 weeks of active treatment in study 0881A1-3338 for any reason or not eligible to continue Etn in study B1801023 asked to enter observational period directly. Subjects from ACT,withdrawal/re-treatment period who discontinued Etn prior to completion of study, asked to participate in observational period. In observational period, all subjects followed up for a maximum of 96 months from the time of initial entry into this study.

Reporting group title	Etanercept

Reporting group description:

Subjects aged <18 years & weighed <=62 kg received Etanercept(Etn)SC dose of 0.8 mg/kg once a week, for active treatment period (ACT) for maximum of 96 months. Subjects who either met Wallace definition for clinically inactive disease for at least 6 months on Etn or who had a good clinical response & would benefit from withdrawal from Etn & were otherwise eligible entered withdrawal period. Subjects requiring re-treatment per investigator's clinical judgment and otherwise eligible entered re-treatment period. Subjects who discontinued Etn prior to completing 96 weeks of active treatment in study 0881A1-3338 for any reason or not eligible to continue Etn in study B1801023 asked to enter observational period directly. Subjects from ACT,withdrawal/re-treatment period who discontinued Etn prior to completion of study, asked to participate in observational period. In observational period, all subjects followed up for a maximum of 96 months from the time of initial entry into this study.

Reporting group title	Etanercept

Reporting group description:

Subjects aged <18 years & weighed <=62 kg received Etanercept (Etn) SC dose of 0.8 mg/kg once a week, for ACT for maximum of 96 months. Subjects who either met Wallace definition for clinically inactive disease for at least 6 months on Etn or who had a good clinical response & would benefit from withdrawal from Etn & were otherwise eligible entered withdrawal period. Subjects requiring re-treatment per investigator's clinical judgment and otherwise eligible entered re-treatment period. Subjects who discontinued Etn prior to completing 96 weeks of active treatment in study 0881A1-3338 for any reason or not eligible to continue Etn in study B1801023 asked to enter observational period directly. Subjects from ACT,withdrawal/re-treatment period who discontinued Etn prior to completion of study, asked to participate in observational period. In observational period, all subjects followed up for a maximum of 96 months from the time of initial entry into this study.

Reporting group title	Etanercept

Reporting group description:

Subjects aged <18 years & weighed <=62 kg received Etanercept (Etn) SC dose of 0.8 mg/kg once a week, for ACT for maximum of 96 months. Subjects who either met Wallace definition for clinically inactive disease for at least 6 months on Etn or who had a good clinical response & would benefit from withdrawal from Etn & were otherwise eligible entered withdrawal period. Subjects requiring re-treatment per investigator's clinical judgment and otherwise eligible entered re-treatment period. Subjects who discontinued Etn prior to completing 96 weeks of active treatment in study 0881A1-3338 for any reason or not eligible to continue Etn in study B1801023 asked to enter observational period directly. Subjects from ACT, withdrawal/re-treatment period who discontinued Etn prior to completion of study, asked to participate in observational period. In observational period, all subjects followed up for a maximum of 96 months from the time of initial entry into this study.

Reporting group title	Etanercept

Reporting group description:

Subjects aged <18 years & weighed <=62 kg received Etanercept (Etn) SC dose of 0.8 mg/kg once a week, for ACT for maximum of 96 months. Subjects who either met Wallace definition for clinically inactive disease for at least 6 months on Etn or who had a good clinical response & would benefit from withdrawal from Etn & were otherwise eligible entered withdrawal period. Subjects requiring re-treatment per investigator's clinical judgment and otherwise eligible entered re-treatment period. Subjects who discontinued Etn prior to completing 96 weeks of active treatment in study 0881A1-3338 for any reason or not eligible to continue Etn in study B1801023 asked to enter observational period directly. Subjects from ACT, withdrawal/re-treatment period who discontinued Etn prior to completion of study, asked to participate in observational period. In observational period, all subjects followed up for a maximum of 96 months from the time of initial entry into this study.

Subject analysis set title	Etanercept: Active Treatment Period
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects aged <18 years and weighed less than or equal to 62 kg received Etanercept as a SC dose of 0.8 mg/kg once a week (for up to a maximum dose of 50 mg once weekly), for an active treatment period for a maximum of 96 months.

Subject analysis set title	Etanercept: Withdrawal Period
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects who either completed 96 weeks of treatment in study 0881A-3338 or were enrolled in the active treatment period of study B1801023 and who had either met the Wallace definition for clinically inactive disease for at least 6 months on Etanercept or who had a good clinical response and would benefit from withdrawal from Etanercept and were otherwise eligible entered the withdrawal period.

Subject analysis set title	Etanercept: Re-treatment Period
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects requiring re-treatment per the investigator’s clinical judgment and were otherwise eligible entered the Re-treatment period.

Subject analysis set title	Etanercept: Observational Period
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects who discontinued Etanercept prior to completing 96 weeks of active treatment in study 0881A1-3338 for any reason or not eligible to continue Etanercept in study B1801023 asked to enter the observational period directly. Subjects from active treatment, withdrawal or re-treatment period who discontinued Etanercept prior to the completion of the study, asked to participate in the observational period. In observational period, all subjects followed up for a maximum of 96 months from the time of initial entry into this study.

Subject analysis set title	Enthesitis-Related Arthritis
Subject analysis set type	Full analysis

Subject analysis set description:

To be diagnosed with enthesitis-related arthritis (ERA) per the International League Associations for Rheumatology (ILAR) criteria, a subject must have had arthritis and enthesitis, or arthritis or enthesitis plus 2 of the following: 1) presence of or a history of sacroiliac joint tenderness and/or inflammatory lumbosacral pain; 2) the presence of human leukocyte antigen, subtype B, number 27 antigen (HLA-B27); 3) onset of arthritis in a male over 6 years of age; 4) acute (symptomatic) anterior uveitis; 5) a history of ankylosing spondylitis, ERA, sacroiliitis with inflammatory bowel disease, Reiter’s syndrome, or acute anterior uveitis in a first-degree relative.

Subject analysis set title	Psoriatic Arthritis (PsA)
Subject analysis set type	Full analysis

Subject analysis set description:

To be diagnosed with psoriatic arthritis (PsA) per the International League Associations for Rheumatology (ILAR) criteria, a subject must have had arthritis and psoriasis, or arthritis plus at least 2 of the following: 1) dactylitis; 2) nail pitting or onycholysis; 3) psoriasis in a first-degree relative.

Subject analysis set title	All Periods (Parent and Extension Study)
Subject analysis set type	Full analysis

Subject analysis set description:

Full analysis set (FAS) includes all subjects in the parent study (0881A1-3338-WW) who received at least 1 dose of investigational product regardless of whether they received any investigational product during the extension study.

Subject analysis set title	Etanercept: Withdrawal/Re-treatment Period
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects who either completed 96 weeks of treatment in study 0881A-3338 or were enrolled in the active treatment period of study B1801023 and who had either met the Wallace definition for clinically inactive disease for at least 6 months on Etanercept or who had a good clinical response and would benefit from withdrawal from Etanercept and were otherwise eligible entered the withdrawal period. Subjects requiring re-treatment per the investigator’s clinical judgment and were otherwise eligible entered the Re-treatment period.

Primary: Number of Subjects With Malignancy: All Periods: Parent and Extension Study

End point title	Number of Subjects With Malignancy: All Periods: Parent and Extension Study[1]

End point description:

Malignancy event included Hodgkin's disease. FAS includes all subjects in the parent study (0881A1-3338-WW) who received at least 1 dose of investigational product regardless of whether they received any investigational product during the extension study.

End point type	Primary

End point timeframe:

Baseline up to Month 96

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 analysis was done for this endpoint

End point values	All Periods (Parent and Extension Study)			
Subject group type	Subject analysis set			
Number of subjects analysed	127			
Units: Subjects	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Serious Adverse Events: All Periods: Parent and Extension Study

End point title	Number of Subjects With Serious Adverse Events: All Periods: Parent and Extension Study

End point description:

A serious adverse event (SAE) was an adverse event (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. FAS includes all subjects in the parent study (0881A1-3338-WW) who received at least 1 dose of investigational product regardless of whether they received any investigational product during the extension study.

End point type	Secondary

End point timeframe:

Baseline up to Month 96

End point values	All Periods (Parent and Extension Study)			
Subject group type	Subject analysis set			
Number of subjects analysed	127			
Units: Subjects	45			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Serious Infections: All Periods: Parent and Extension Study

End point title	Number of Subjects With Serious Infections: All Periods: Parent and Extension Study

End point description:

Serious infections were defined as any infections those were life threatening or resulted in disability, infections requiring intravenous antibiotic treatment and hospitalization. The full analysis set included all subjects in the parent study (0881A1-3338-WW) who received at least 1 dose of investigational product regardless of whether they received any investigational product during the extension study.

End point type	Secondary

End point timeframe:

Baseline up to Month 96

End point values	All Periods (Parent and Extension Study)			
Subject group type	Subject analysis set			
Number of subjects analysed	127			
Units: Subjects	14			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Medically Important Infections: All Periods: Parent and Extension Study

End point title	Number of Subjects With Medically Important Infections: All Periods: Parent and Extension Study

End point description:

Medically important infections were defined as an infection requiring parenteral [intravenous (IV), intramuscular (IM)] anti-infective agent(s) and/or hospitalization. The full analysis set included all subjects in the parent study who received at least 1 dose of investigational product regardless of whether they received any investigational product during the extension study.

End point type	Secondary

End point timeframe:

Baseline upto Month 96

End point values	All Periods (Parent and Extension Study)			
Subject group type	Subject analysis set			
Number of subjects analysed	127			
Units: Subjects	12			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Infections: All Periods: Parent and Extension Study

End point title	Number of Subjects With Infections: All Periods: Parent and Extension Study

End point description:

The full analysis set included all subjects in the parent study who received at least 1 dose of investigational product regardless of whether they received any investigational product during the extension study.

End point type	Secondary

End point timeframe:

Baseline upto Month 96

End point values	All Periods (Parent and Extension Study)			
Subject group type	Subject analysis set			
Number of subjects analysed	127			
Units: Subjects	111			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Infections and Injection Site Reactions: All Periods: Extension Study

End point title	Number of Subjects With Infections and Injection Site Reactions: All Periods: Extension Study

End point description:

Adverse events (AE) are any untoward medical occurrence in a subject who received study medication without regard to possibility of causal relationship to it. Adverse events included infections, infections considered preventable by vaccination and injection site reactions. The analysis set included all subjects enrolled in the extension study.

End point type	Secondary

End point timeframe:

Baseline up to Month 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	109			
Units: Subjects				
Treatment emergent infections	67			
Injection site reactions	16			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Infections: Withdrawal Period: Extension Study

End point title	Number of Subjects With Infections: Withdrawal Period: Extension Study

End point description:

Adverse event (AE) are any untoward medical occurrence in a subject who received study medication without regard to possibility of causal relationship to it. Adverse events included infections, infections considered preventable by vaccination and injection site reactions. Analysis population included subjects enrolled in parent study and entered in withdrawal/re-treatment period.

End point type	Secondary

End point timeframe:

Withdrawal from study treatment to end of study (From Day 1 up to Month 96)

End point values	Etanercept: Withdrawal Period			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Subjects				
Treatment emergent infections	8			
Infections considered preventable by vaccination	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Withdrawn Due to Adverse Events: All Periods: Parent and Extension Study

End point title	Number of Subjects Withdrawn Due to Adverse Events: All Periods: Parent and Extension Study

End point description:

In this endpoint, subjects withdrawn due adverse events were reported. The analysis set included all subjects enrolled in the extension study.

End point type	Secondary

End point timeframe:

Baseline up to Month 96

End point values	All Periods (Parent and Extension Study)			
Subject group type	Subject analysis set			
Number of subjects analysed	127			
Units: Subjects				
Due to infections	3			
Due to other adverse events	14			
Due to injection site reactions	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Withdrawn Due to Adverse Events: Withdrawal Period: Extension Study

End point title	Number of Subjects Withdrawn Due to Adverse Events: Withdrawal Period: Extension Study

End point description:

Subjects withdrawn due to adverse events were reported. Analysis population included subjects enrolled in parent study and entered in withdrawal/re-treatment period.

End point type	Secondary

End point timeframe:

Baseline up to Month 96

End point values	Etanercept: Withdrawal Period			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Subjects	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Grade 3 or Grade 4 Laboratory Abnormalities: All Periods: Extension Study

End point title	Number of Subjects With Grade 3 or Grade 4 Laboratory Abnormalities: All Periods: Extension Study

End point description:

Clinically notable shifts were defined as worsening by at least 2 grades or to >= grade 3. Severity was graded as Grade 1: asymptomatic or mild symptoms, clinical or diagnostic observations only, intervention not indicated; Grade 2: moderate, minimal, local or noninvasive intervention indicated, limiting age-appropriate instrumental activities of daily life (ADL); Grade 3: severe or medically significant but not immediately life-threatening, hospitalization or prolongation of existing hospitalization indicated, disabling, limiting self-care ADL; Grade 4: life-threatening consequence, urgent intervention indicated; Grade 5: death related to AE. FAS includes all subjects in the parent study (0881A1-3338-WW) who received at least 1 dose of investigational product regardless of whether they received any investigational product during the extension study. Here, "n" signifies subjects evaluable for specific parameter.

End point type	Secondary

End point timeframe:

Baseline up to Month 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	109			
Units: Subjects				
Grade 3	2			
Grade 4	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Z-Score at Month 12, 24, 36, 48, 60, 72, 84, 96: All Periods: Extension Study

End point title	Change From Baseline in Z-Score at Month 12, 24, 36, 48, 60, 72, 84, 96: All Periods: Extension Study

End point description:

Growth parameters included weight, height and body-mass index (BMI) were compared to the standard growth data by using Z-Score. Z-score is a statistical measure to evaluate how a single data point or mean compares to a standard. A Z-Score describes whether a mean is above or below the standard and how unusual the measurement is. Z-scores range from -3 to +3. A Z-score of 0 indicates the same mean, >0 a greater mean, and <0 a lesser mean than the standard. In this study, infant growth parameters were compared to a standard defined by Centers for Disease Control's growth charts. The analysis set included all subjects enrolled in extension study.

End point type	Secondary

End point timeframe:

Baseline, Month 12, 24, 36, 48, 60, 72, 84, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	97			
Units: z-score				
arithmetic mean (standard deviation)				
At Baseline; Height (n=97)	0.22 (± 0.43)			
At Month 12; Height (n=88)	0.22 (± 0.46)			
At Month 24; Height (n=55)	0.17 (± 0.56)			
At Month 36; Height (n=43)	0.21 (± 0.66)			
At Month 48; Height (n=28)	0.19 (± 0.58)			
At Month 60; Height (n=13)	0.25 (± 0.67)			
At Month 72; Height (n=10)	0.30 (± 0.90)			
At Month 84; Height (n=5)	0.09 (± 0.53)			
At Month 96; Height (n=4)	0.16 (± 0.63)			
At Baseline; Weight (n=99)	0.09 (± 0.57)			
At Month 12; Weight (n=81)	0.05 (± 0.60)			
At Month 24; Weight (n=53)	-0.04 (± 0.68)			
At Month 36; Weight (n=40)	-0.06 (± 0.72)			
At Month 48; Weight (n=25)	-0.00 (± 0.71)			
At Month 60; Weight (n=13)	0.25 (± 0.64)			
At Month 72; Weight (n=10)	0.45 (± 0.74)			
At Month 84; Weight (n=5)	0.04 (± 0.62)			
At Month 96; Weight (n=4)	0.27 (± 0.68)			
At Baseline; BMI (n=97)	-0.02 (± 0.80)			
At Month 12; BMI (n=88)	-0.03 (± 0.77)			
At Month 24; BMI (n=55)	-0.13 (± 0.86)			
At Month 36; BMI (n=43)	-0.19 (± 0.79)			
At Month 48; BMI (n=28)	-0.17 (± 0.87)			
At Month 60; BMI (n=13)	0.02 (± 0.86)			
At Month 72; BMI (n=10)	0.26 (± 1.00)			
At Month 84; BMI (n=5)	0.00 (± 0.99)			
At Month 96; BMI (n=4)	0.27 (± 1.21)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Z-Score at Month 12, 24, 36, 42, 48, 60, 72: Withdrawal Period: Extension Study

End point title	Change From Baseline in Z-Score at Month 12, 24, 36, 42, 48, 60, 72: Withdrawal Period: Extension Study

End point description:

Growth parameters included weight, height and BMI were compared to the standard growth data by using Z-Score. Z-score is a statistical measure to evaluate how a single data point or mean compares to a standard. A Z-Score describes whether a mean is above or below the standard and how unusual the measurement is. Z-scores range from -3 to +3. A Z-score of 0 indicates the same mean, >0 a greater mean, and <0 a lesser mean than the standard. In this study, infant growth parameters were compared to a standard defined by Centers for Disease Control's growth charts. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. 99999 signifies that standard deviation was not estimable as only 1 subject was evaluated. Data for this endpoint was estimable till week 72 only.

End point type	Secondary

End point timeframe:

Baseline, Month 12, 24, 36, 42, 48, 60, 72

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: z-score				
arithmetic mean (standard deviation)				
At Month 12; Height (n=9)	-0.10 (± 0.21)			
At Month 24; Height (n=5)	-0.13 (± 0.28)			
At Month 36; Height (n=3)	0.03 (± 0.05)			
At Month 48; Height (n=1)	0.26 (± 99999)			
At Month 60; Height (n=1)	0.41 (± 99999)			
At Month 72; Height (n=1)	0.52 (± 99999)			
At Month 12; Weight (n=9)	-0.07 (± 0.25)			
At Month 24; Weight (n=4)	-0.09 (± 0.35)			
At Month 36; Weight (n=3)	-0.05 (± 0.42)			
At Month 48; Weight (n=1)	0.22 (± 99999)			
At Month 60; Weight (n=1)	0.46 (± 99999)			
At Month 72; Weight (n=1)	0.60 (± 99999)			
At Month 12; BMI (n=9)	-0.04 (± 0.24)			
At Month 24; BMI (n=5)	-0.14 (± 0.30)			
At Month 36; BMI (n=3)	0.06 (± 0.51)			
At Month 48; BMI (n=1)	0.51 (± 99999)			
At Month 60; BMI (n=1)	0.72 (± 99999)			
At Month 72; BMI (n=1)	0.72 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Z-Score at Month 12, 24, 36, 42, 48, 60: Re-treatment Period: Extension Study

End point title	Change From Baseline in Z-Score at Month 12, 24, 36, 42, 48, 60: Re-treatment Period: Extension Study

End point description:

Growth parameters included weight, height and body-mass index (BMI) were compared to the standard growth data by using Z-Score. Z-score is a statistical measure to evaluate how a single data point or mean compares to a standard. A Z-Score describes whether a mean is above or below the standard and how unusual the measurement is. Z-scores range from -3 to +3. A Z-score of 0 indicates the same mean, >0 a greater mean, and <0 a lesser mean than the standard. In this study, infant growth parameters were compared to a standard defined by Centers for Disease Control's growth charts. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Data for this endpoint was estimable till Week 60 only.

End point type	Secondary

End point timeframe:

Baseline, Month 12, 24, 36, 42, 48, 60

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	9			
Units: z-score				
arithmetic mean (standard deviation)				
At Month 12; Height (n=9)	-0.21 (± 0.31)			
At Month 24; Height (n=8)	-0.19 (± 0.43)			
At Month 36; Height (n=6)	-0.19 (± 0.41)			
At Month 48; Height (n=4)	0.07 (± 0.12)			
At Month 60; Height (n=2)	-0.08 (± 0.27)			
At Month 96; Height (n=0)	99999 (± 99999)			
At Month 12; Weight (n=9)	0.08 (± 0.26)			
At Month 24; Weight (n=8)	-0.07 (± 0.32)			
At Month 36; Weight (n=7)	-0.15 (± 0.43)			
At Month 48; Weight (n=4)	-0.33 (± 0.58)			
At Month 60; Weight (n=2)	-0.57 (± 0.12)			
At Month 72; Weight (n=1)	-1.06 (± 99999)			
At Month 96; Weight (n=0)	99999 (± 99999)			
At Month 12; BMI (n=9)	0.27 (± 0.60)			
At Month 24; BMI (n=8)	0.01 (± 0.71)			
At Month 36; BMI (n=6)	-0.17 (± 0.83)			
At Month 48; BMI (n=4)	-0.59 (± 0.90)			
At Month 60; BMI (n=2)	-0.85 (± 0.16)			
At Month 96; BMI (n=0)	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Tanner Assessment Score for Subjects Aged <18 Years at Month 96: All Periods: Extension Study

End point title	Change from Baseline in Tanner Assessment Score for Subjects Aged <18 Years at Month 96: All Periods: Extension Study

End point description:

Tanner assessment score: used to document the stage of development of secondary sexual characteristics. Female pubertal development staged by pubic hair development and breast size; male pubertal development staged by size of the genitalia and development of pubic hair. Rated in 5 stages: stage 1 (no development) to 5 (adult-like development in quantity and size). The analysis set included all subjects enrolled in the extension study.

End point type	Secondary

End point timeframe:

Baseline, Month 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Units on a scale				
arithmetic mean (standard deviation)	4 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving American College of Rheumatology 30% (ACR30) Pediatric Response at Month Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96: All Periods: Extension Study

End point title	Percentage of Subjects Achieving American College of Rheumatology 30% (ACR30) Pediatric Response at Month Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96: All Periods: Extension Study

End point description:

ACR 30 pediatric response: greater than or equal to (>=) 30% improvement from baseline in 3 of 6 criteria with worsening > 30% in no more than 1 of 6 criteria: 1) physician's global assessment of disease activity, 2) parent/patient global assessment of arthritis pain, 3) childhood health assessment questionnaire (CHAQ) 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein. PGAwasmeasuredonVAS rangingfrom0to10,higherscoresindicatedgreaterdiseaseactivity. Patient/ParentGlobalAssessmentassessed by subject's parentusingVAS ranging from 0to10, 0=very well and 10=very poor. CHAQscore:0=no difficultyto3=extremedifficulty. Jointswithactivearthritisdefinedasjointsthatwereswollenoraccompanied by pain and/or tenderness. Decrease in CRP indicated reduction in inflammation and therefore improvement. The analysis set included all subjects enrolled in the extension study. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	61			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 6 (n=23)	95.7 (78.1 to 99.9)			
Month 12 (n=61)	98.4 (91.2 to 100)			
Month 18 (n=61)	96.7 (88.7 to 99.6)			
Month 24 (n=55)	100 (93.5 to 100)			

Month 30 (n=53)	100 (93.3 to 100)			
Month 36 (n=48)	100 (92.6 to 100)			
Month 42 (n=46)	95.7 (85.2 to 99.5)			
Month 48 (n=43)	97.7 (87.7 to 99.9)			
Month 54 (n=38)	100 (90.7 to 100)			
Month 60 (n=34)	100 (89.7 to 100)			
Month 66 (n=31)	100 (88.8 to 100)			
Month 72 (n=25)	100 (86.3 to 100)			
Month 78 (n=24)	100 (85.8 to 100)			
Month 84 (n=21)	100 (83.9 to 100)			
Month 90 (n=22)	100 (84.6 to 100)			
Month 96 (n=16)	100 (79.4 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving American College of Rheumatology 30% (ACR30) Pediatric Response at Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72: Withdrawal Period: Extension Study

End point title	Percentage of Subjects Achieving American College of Rheumatology 30% (ACR30) Pediatric Response at Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72: Withdrawal Period: Extension Study

End point description:

ACR 30 pediatric response: greater than or equal to (>=) 30% improvement from baseline in 3 of 6 criteria with worsening > 30% in no more than 1 of 6 criteria: 1) physician's global assessment of disease activity, 2) parent/patient global assessment of arthritis pain, 3) childhood health assessment questionnaire (CHAQ) 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein. t. The analysis set included all subjects enrolled in the extension study. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Here, "n" signifies subjects evaluable at specific time points. Data for this end point was estimable till Week72 only.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 1 (n=23)	95.7 (78.1 to 99.9)			
Month 3 (n=15)	100 (78.2 to 100)			
Month 6 (n=11)	100 (71.5 to 100)			
Month 9 (n=9)	88.9 (51.8 to 99.7)			
Month 12 (n=9)	88.9 (51.8 to 99.7)			
Month 18 (n=8)	100 (63.1 to 100)			
Month 24 (n=5)	100 (47.8 to 100)			
Month 30 (n=4)	100 (39.8 to 100)			
Month 36 (n=4)	100 (39.8 to 100)			
Month 42 (n=4)	100 (39.8 to 100)			
Month 48 (n=3)	66.7 (9.4 to 99.2)			
Month 54 (n=1)	100 (2.5 to 100)			
Month 60 (n=2)	100 (15.8 to 100)			
Month 66 (n=1)	100 (2.5 to 100)			
Month 72 (n=1)	100 (2.5 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving American College of Rheumatology 30% (ACR30) Pediatric Response at Month 3, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78: Re-treatment period: Extension Study

End point title	Percentage of Subjects Achieving American College of Rheumatology 30% (ACR30) Pediatric Response at Month 3, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78: Re-treatment period: Extension Study

End point description:

ACR 30 pediatric response: >=30% improvement from baseline in 3 of 6 criteria with worsening > 30% in no more than 1 of 6 criteria:physician's global assessment(PGA) of disease activity, parent/patient global assessment of arthritis pain, childhood health assessment questionnaire (CHAQ), number of active joints, number of joints with limited range of motion and C-reactive protein. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Percentage of subjects				
arithmetic mean (confidence interval 95%)				
Month 3 (n=12)	100 (73.5 to 100)			
Month 6 (n=12)	100 (73.5 to 100)			
Month 9 (n=12)	91.7 (61.5 to 99.8)			
Month 12 (n=11)	90.9 (58.7 to 99.8)			
Month 18 (n=10)	100 (69.2 to 100)			
Month 24 (n=8)	100 (63.1 to 100)			
Month 30 (n=9)	100 (66.4 to 100)			
Month 36 (n=9)	100 (66.4 to 100)			
Month 42 (n=5)	100 (47.8 to 100)			
Month 48 (n=4)	100 (39.8 to 100)			
Month 54 (n=4)	100 (39.8 to 100)			
Month 60 (n=3)	100 (29.2 to 100)			
Month 66 (n=4)	100 (39.8 to 100)			
Month 72 (n=2)	100 (15.8 to 100)			
Month 78 (n=1)	100 (2.5 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving American College of Rheumatology 50% (ACR50) Pediatric Response at Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96: All Periods: Extension Study

End point title	Percentage of Subjects Achieving American College of Rheumatology 50% (ACR50) Pediatric Response at Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96: All Periods: Extension Study

End point description:

ACR Pedi 50 response: >= 50% improvement from baseline in 3 of 6 criteria with worsening >30% in

no more than 1 of 6 criteria: physician's global assessment(PGA) of disease activity, parent/patient global assessment of arthritis pain, childhood health assessment questionnaire (CHAQ), number of active joints, number of joints with limited range of motion and C-reactive protein. The analysis set included all subjects enrolled in extension study. Here, "n" signifies subjects evaluable at specific time points. Here, "overall number of participants analyzed" signifies participants evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	61			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 6 (n=23)	95.7 (78.1 to 99.9)			
Month 12 (n=60)	98.3 (91.1 to 100)			
Month 18 (n=61)	96.7 (88.7 to 99.6)			
Month 24 (n=56)	98.2 (90.4 to 100)			
Month 30 (n=53)	98.1 (89.9 to 100)			
Month 36 (n=47)	100 (92.5 to 100)			
Month 42 (n=46)	93.5 (82.1 to 98.6)			
Month 48 (n=42)	97.6 (87.4 to 99.9)			
Month 54 (n=38)	100 (90.7 to 100)			
Month 60 (n=33)	100 (89.4 to 100)			
Month 66 (n=31)	100 (88.8 to 100)			
Month 72 (n=25)	100 (86.3 to 100)			
Month 78 (n=24)	100 (85.8 to 100)			
Month 84 (n=21)	100 (83.9 to 100)			
Month 90 (n=22)	100 (84.6 to 100)			
Month 96 (n=16)	100 (79.4 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving American College of Rheumatology

50% (ACR50) Pediatric Response at Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72: Withdrawal Period: Extension Study

End point title	Percentage of Subjects Achieving American College of Rheumatology 50% (ACR50) Pediatric Response at Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72: Withdrawal Period: Extension Study

End point description:

ACR Pedi 50 response: >= 50% improvement from baseline in 3 of 6 criteria with worsening >30% in no more than 1 of 6 criteria: physician's global assessment(PGA) of disease activity, parent/patient global assessment of arthritis pain, childhood health assessment questionnaire (CHAQ), number of active joints, number of joints with limited range of motion and C-reactive protein. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Data for this endpoint was estimable till Week 72 only. Here, "n" signifies subjects evaluable at specific time points. Here, "overall number of participants analyzed" signifies participants evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 1 (n=23)	87.0 (66.4 to 97.2)			
Month 3 (n=15)	100 (78.2 to 100)			
Month 6 (n=11)	90.9 (58.7 to 99.8)			
Month 9 (n=9)	88.9 (51.8 to 99.7)			
Month 12 (n=9)	88.9 (51.8 to 99.7)			
Month 18 (n=8)	87.5 (47.3 to 99.7)			
Month 24 (n=5)	100 (47.8 to 100)			
Month 30 (n=4)	100 (39.8 to 100)			
Month 36 (n=3)	100 (29.2 to 100)			
Month 42 (n=4)	100 (39.8 to 100)			
Month 48 (n=3)	66.7 (9.4 to 99.2)			
Month 54 (n=1)	100 (2.5 to 100)			
Month 60 (n=1)	100 (2.5 to 100)			
Month 66 (n=1)	100 (2.5 to 100)			
Month 72 (n=1)	100 (2.5 to 100)			
Month 96 (n=0)	99999 (99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving American College of Rheumatology 50% (ACR50) Pediatric Response at Month 3, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78: Re-treatment Period: Extension Study

End point title	Percentage of Subjects Achieving American College of Rheumatology 50% (ACR50) Pediatric Response at Month 3, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78: Re-treatment Period: Extension Study

End point description:

ACR Pedi 50 response: >= 50% improvement from baseline in 3 of 6 criteria with worsening >30% in no more than 1 of 6 criteria: physician's global assessment(PGA) of disease activity, parent/patient global assessment of arthritis pain, childhood health assessment questionnaire (CHAQ), number of active joints, number of joints with limited range of motion and C-reactive protein. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Only data collected in the withdrawal period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 3, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 3 (n=12)	100 (73.5 to 100)			
Month 6 (n=12)	100 (73.5 to 100)			
Month 9 (n=12)	91.7 (61.5 to 99.8)			
Month 12 (n=11)	90.9 (58.7 to 99.8)			
Month 18 (n=10)	100 (69.2 to 100)			
Month 24 (n=8)	87.5 (47.3 to 99.7)			
Month 30 (n=9)	100 (66.4 to 100)			
Month 36 (n=9)	100 (66.4 to 100)			
Month 42 (n=5)	100 (47.8 to 100)			

Month 48 (n=4)	100 (39.8 to 100)			
Month 54 (n=4)	100 (39.8 to 100)			
Month 60 (n=3)	100 (29.2 to 100)			
Month 66 (n=4)	100 (39.8 to 100)			
Month 72 (n=2)	100 (15.8 to 100)			
Month 78 (n=1)	100 (2.5 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving American College of Rheumatology 70% (ACR70) Pediatric Response at Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96: All Periods: Extension Study

End point title	Percentage of Subjects Achieving American College of Rheumatology 70% (ACR70) Pediatric Response at Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96: All Periods: Extension Study

End point description:

ACR Pedi 70 response: >=70% improvement from baseline in 3 of 6 criteria with worsening > 30% in no more than 1 of 6 criteria:PGA of disease activity, parent/patient global assessment of arthritis pain, childhood health assessment questionnaire (CHAQ), number of active joints, number of joints with limited range of motion and C-reactive protein. The analysis set included all subjects enrolled in the extension study. Here, "overall number of participants analyzed" signifies participants evaluable for this outcome measure. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	62			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 6 (n=23)	95.7 (78.1 to 99.9)			
Month 12 (n=62)	87.1 (76.1 to 94.3)			
Month 18 (n=62)	88.7 (78.1 to 95.3)			
Month 24 (n=55)	89.3 (78.1 to 96.0)			
Month 30 (n=52)	88.5 (76.6 to 95.6)			
Month 36 (n=47)	89.4 (76.9 to 96.5)			

Month 42 (n=43)	88.4 (74.9 to 96.1)			
Month 48 (n=41)	95.1 (83.5 to 99.4)			
Month 54 (n=37)	100 (90.5 to 100)			
Month 60 (n=33)	100 (89.4 to 100)			
Month 66 (n=31)	100 (88.8 to 100)			
Month 72 (n=26)	96.2 (80.4 to 99.9)			
Month 78 (n=23)	100 (85.2 to 100)			
Month 84 (n=20)	100 (83.2 to 100)			
Month 90 (n=22)	90.9 (70.8 to 98.9)			
Month 96 (n=15)	93.3 (68.1 to 99.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving American College of Rheumatology 70% (ACR70) Pediatric Response at Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72: Withdrawal Period: Extension Study

End point title	Percentage of Subjects Achieving American College of Rheumatology 70% (ACR70) Pediatric Response at Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72: Withdrawal Period: Extension Study

End point description:

ACR Pedi 70 response: >=70% improvement from baseline in 3 of 6 criteria with worsening >30% in no more than 1 of 6 criteria: PGA of disease activity, parent/patient global assessment of arthritis pain, childhood health assessment questionnaire (CHAQ), number of active joints, number of joints with limited range of motion and C-reactive protein. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Data for this endpoint was estimable till Week 72 only. Here, "overall number of participants analyzed" signifies participants evaluable for this outcome measure. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 1 (n=22)	77.3 (54.6 to 92.2)			
Month 3 (n=15)	93.3 (68.1 to 99.8)			

Month 6 (n=11)	90.9 (58.7 to 99.8)			
Month 9 (n=9)	88.9 (51.8 to 99.7)			
Month 12 (n=9)	88.9 (51.8 to 99.7)			
Month 18 (n=7)	85.7 (42.1 to 99.6)			
Month 24 (n=5)	100 (47.8 to 100)			
Month 30 (n=4)	100 (39.8 to 100)			
Month 36 (n=3)	100 (29.2 to 100)			
Month 42 (n=4)	100 (39.8 to 100)			
Month 48 (n=3)	66.7 (9.4 to 99.2)			
Month 54 (n=1)	100 (2.5 to 100)			
Month 60 (n=1)	100 (2.5 to 100)			
Month 66 (n=1)	100 (2.5 to 100)			
Month 72 (n=1)	100 (2.5 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving American College of Rheumatology 70% (ACR70) Pediatric Response at Month 3, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78: Re-treatment Period: Extension Study

End point title	Percentage of Subjects Achieving American College of Rheumatology 70% (ACR70) Pediatric Response at Month 3, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78: Re-treatment Period: Extension Study

End point description:

ACR Pedi 70 response: >=70% improvement from baseline in 3 of 6 criteria with worsening >30% in no more than 1 of 6 criteria: PGA of disease activity, parent/patient global assessment of arthritis pain, childhood health assessment questionnaire (CHAQ), number of active joints, number of joints with limited range of motion and C-reactive protein. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Only data collected in the withdrawal period was included. Data for this endpoint was estimable till Week 78 only. Here, "overall number of participants analyzed" signifies participants evaluable for this outcome measure. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 3, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 3 (n=12)	91.7 (61.5 to 99.8)			
Month 6 (n=12)	83.3 (51.6 to 97.9)			
Month 9 (n=11)	81.8 (48.2 to 97.7)			
Month 12 (n=11)	81.8 (48.2 to 97.7)			
Month 18 (n=10)	80.0 (44.4 to 97.5)			
Month 24 (n=8)	75.0 (34.9 to 96.8)			
Month 30 (n=9)	66.7 (29.9 to 92.5)			
Month 36 (n=9)	88.9 (51.8 to 99.7)			
Month 42 (n=6)	83.3 (35.9 to 99.6)			
Month 48 (n=4)	100 (39.8 to 100)			
Month 54 (n=4)	100 (39.8 to 100)			
Month 60 (n=3)	100 (29.2 to 100)			
Month 66 (n=3)	100 (29.2 to 100)			
Month 72 (n=2)	100 (15.8 to 100)			
Month 78 (n=1)	100 (2.5 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving American College of Rheumatology 90% (ACR90) Pediatric Response at Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96: All Periods: Extension Study

End point title	Percentage of Subjects Achieving American College of Rheumatology 90% (ACR90) Pediatric Response at Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96: All Periods: Extension Study

End point description:

ACR Pedi 90 response: >=90% improvement from baseline in 3 of 6 criteria with worsening >30% in no more than 1 of 6 criteria: PGA of disease activity, parent/patient global assessment of arthritis pain, childhood health assessment questionnaire (CHAQ), number of active joints, number of joints with limited range of motion and C-reactive protein. The analysis set included all subjects enrolled in the extension study. ere, "overall number of participants analyzed" signifies participants evaluable for this outcome measure. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:
Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	62			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 6 (n=25)	64.0 (42.5 to 82.0)			
Month 12 (n=57)	70.2 (56.6 to 81.6)			
Month 18 (n=62)	72.6 (59.8 to 83.1)			
Month 24 (n=54)	64.8 (50.6 to 77.3)			
Month 30 (n=52)	63.5 (49.0 to 76.4)			
Month 36 (n=45)	71.1 (55.7 to 83.6)			
Month 42 (n=43)	67.4 (51.5 to 80.9)			
Month 48 (n=41)	65.9 (49.4 to 79.9)			
Month 54 (n=31)	77.4 (58.9 to 90.4)			
Month 60 (n=29)	89.7 (72.6 to 97.8)			
Month 66 (n=24)	87.5 (67.6 to 97.3)			
Month 72 (n=24)	75.0 (53.3 to 90.2)			
Month 78 (n=17)	100 (80.5 to 100)			
Month 84 (n=18)	77.8 (52.4 to 93.6)			
Month 90 (n=20)	90.0 (68.3 to 98.8)			
Month 96 (n=15)	86.7 (59.5 to 98.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving American College of Rheumatology 90% (ACR90) Pediatric Response at Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72: Withdrawal Period: Extension Study

End point title	Percentage of Subjects Achieving American College of Rheumatology 90% (ACR90) Pediatric Response at Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72: Withdrawal Period: Extension Study

End point description:

ACR Pedi 90 response: >=90% improvement from baseline in 3 of 6 criteria with worsening >30% in no more than 1 of 6 criteria:PGA of disease activity, parent/patient global assessment of arthritis pain, childhood health assessment questionnaire (CHAQ), number of active joints, number of joints with limited range of motion and C-reactive protein. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Here, "overall number of participants analyzed" signifies participants evaluable for this outcome measure. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 1 (n=21)	66.7 (43.0 to 85.4)			
Month 3 (n=14)	71.4 (41.9 to 91.6)			
Month 6 (n=10)	70.0 (34.8 to 93.3)			
Month 9 (n=8)	75.0 (34.9 to 96.8)			
Month 12 (n=8)	87.5 (47.3 to 99.7)			
Month 18 (n=8)	75.0 (34.9 to 96.8)			
Month 24 (n=4)	100 (39.8 to 100)			
Month 30 (n=4)	100 (39.8 to 100)			
Month 36 (n=4)	75.0 (19.4 to 99.4)			
Month 42 (n=4)	75.0 (19.4 to 99.4)			
Month 48 (n=3)	66.7 (9.4 to 99.2)			
Month 54 (n=2)	50.0 (1.3 to 98.7)			
Month 60 (n=1)	100 (2.5 to 100)			
Month 66 (n=1)	100 (2.5 to 100)			
Month 72 (n=2)	50.0 (1.3 to 98.7)			
Month 78 (n=1)	0.0 (0.0 to 97.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving American College of Rheumatology 90% (ACR90) Pediatric Response at Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78: Re-treatment Period: Extension Study

End point title	Percentage of Subjects Achieving American College of Rheumatology 90% (ACR90) Pediatric Response at Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78: Re-treatment Period: Extension Study

End point description:

ACR Pedi 90 response: >=90% improvement from baseline in 3 of 6 criteria with worsening >30% in no more than 1 of 6 criteria:PGA of disease activity, parent/patient global assessment of arthritis pain, childhood health assessment questionnaire (CHAQ), number of active joints, number of joints with limited range of motion and C-reactive protein. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Data for this endpoint was estimable till Week 72 only. Here, "overall number of participants analyzed" signifies participants evaluable for this outcome measure. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 3 (n=11)	63.6 (30.8 to 89.1)			
Month 6 (n=12)	66.7 (34.9 to 90.1)			
Month 9 (n=12)	66.7 (34.9 to 90.1)			
Month 12 (n=10)	70.0 (34.8 to 93.3)			
Month 18 (n=8)	75.0 (34.9 to 96.8)			
Month 24 (n=7)	57.1 (18.4 to 90.1)			
Month 30 (n=8)	62.5 (24.5 to 91.5)			
Month 36 (n=8)	87.5 (47.3 to 99.7)			
Month 42 (n=5)	60.0 (14.7 to 94.7)			
Month 48 (n=4)	25.0 (0.6 to 80.6)			
Month 54 (n=4)	50.0 (6.8 to 93.2)			
Month 60 (n=4)	50.0 (6.8 to 93.2)			
Month 66 (n=4)	50.0 (6.8 to 93.2)			
Month 72 (n=3)	33.3 (0.8 to 90.6)			
Month 78 (n=1)	100 (2.5 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving American College of Rheumatology 100% (ACR100) Pediatric Response at Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96: All Periods: Extension Study

End point title	Percentage of Subjects Achieving American College of Rheumatology 100% (ACR100) Pediatric Response at Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96: All Periods: Extension Study

End point description:

ACR Pedi 100 response: 100% improvement from baseline in 3 of 6 criteria with worsening >30% in no more than 1 of 6 criteria: PGA of disease activity, parent/patient global assessment of arthritis pain, childhood health assessment questionnaire (CHAQ), number of active joints, number of joints with limited range of motion and C-reactive protein. The analysis set included all subjects enrolled in the extension study. Here, "overall number of participants analyzed" signifies participants evaluable for this outcome measure. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 6 (n=25)	44.0 (24.4 to 65.1)			
Month 12 (n=54)	51.9 (37.8 to 65.7)			
Month 18 (n=60)	55.0 (41.6 to 67.9)			
Month 24 (n=55)	45.5 (32.0 to 59.4)			
Month 30 (n=52)	40.4 (27.0 to 54.9)			
Month 36 (n=36)	52.8 (35.5 to 69.6)			
Month 42 (n=37)	48.6 (31.9 to 65.6)			
Month 48 (n=35)	48.6 (31.4 to 66.0)			
Month 54 (n=30)	56.7 (37.4 to 74.5)			
Month 60 (n=24)	62.5 (40.6 to 81.2)			

Month 66 (n=21)	57.1 (34.0 to 78.2)			
Month 72 (n=18)	38.9 (17.3 to 64.3)			
Month 78 (n=16)	75.0 (47.6 to 92.7)			
Month 84 (n=15)	53.3 (26.6 to 78.7)			
Month 90 (n=14)	71.4 (41.9 to 91.6)			
Month 96 (n=9)	77.8 (40.0 to 97.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving American College of Rheumatology 100% (ACR100) Pediatric Response at Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72: Withdrawal Period: Extension Study

End point title	Percentage of Subjects Achieving American College of Rheumatology 100% (ACR100) Pediatric Response at Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72: Withdrawal Period: Extension Study

End point description:

ACR Pedi 100 response: 100% improvement from baseline in 3 of 6 criteria with worsening >30% in no more than 1 of 6 criteria:PGA of disease activity, parent/patient global assessment of arthritis pain, childhood health assessment questionnaire (CHAQ), number of active joints, number of joints with limited range of motion and C-reactive protein. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Data for this endpoint was estimable till Week 72 only. Here, "overall number of participants analyzed" signifies participants evaluable for this outcome measure. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 1 (n=21)	61.9 (38.4 to 81.9)			
Month 3 (n=14)	64.3 (35.1 to 87.2)			
Month 6 (n=11)	63.6 (30.8 to 89.1)			
Month 9 (n=9)	66.7 (29.9 to 92.5)			
Month 12 (n=9)	77.8 (40.0 to 97.2)			
Month 18 (n=9)	66.7 (29.9 to 92.5)			

Month 24 (n=5)	80.0 (28.4 to 99.5)			
Month 30 (n=5)	80.0 (28.4 to 99.5)			
Month 36 (n=4)	75.0 (19.4 to 99.4)			
Month 42 (n=5)	60.0 (14.7 to 94.7)			
Month 48 (n=4)	50.0 (6.8 to 93.2)			
Month 54 (n=2)	50.0 (1.3 to 98.7)			
Month 60 (n=1)	100 (2.5 to 100)			
Month 66 (n=1)	100 (2.5 to 100)			
Month 72 (n=2)	50.0 (1.3 to 98.7)			
Month 78 (n=1)	0.0 (0.0 to 97.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving American College of Rheumatology 100% (ACR100) Pediatric Response at Month 3, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78: Re-treatment Period: Extension Study

End point title	Percentage of Subjects Achieving American College of Rheumatology 100% (ACR100) Pediatric Response at Month 3, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78: Re-treatment Period: Extension Study

End point description:

ACR Pedi 100 response: 100% improvement from baseline in 3 of 6 criteria with worsening >30% in no more than 1 of 6 criteria:PGA of disease activity, parent/patient global assessment of arthritis pain, childhood health assessment questionnaire (CHAQ), number of active joints, number of joints with limited range of motion and C-reactive protein. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Data for this endpoint was estimable till Week 78 only. Here, "overall number of participants analyzed" signifies participants evaluable for this outcome measure. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 3, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 3 (n=11)	54.5 (23.4 to 83.3)			

Month 6 (n=12)	50.0 (21.1 to 78.9)			
Month 9 (n=11)	63.6 (30.8 to 89.1)			
Month 12 (n=8)	62.5 (24.5 to 91.5)			
Month 18 (n=8)	75.0 (34.9 to 96.8)			
Month 24 (n=7)	57.1 (18.4 to 90.1)			
Month 30 (n=7)	57.1 (18.4 to 90.1)			
Month 36 (n=8)	87.5 (47.3 to 99.7)			
Month 42 (n=5)	60.0 (14.7 to 94.7)			
Month 48 (n=4)	25.0 (0.6 to 80.6)			
Month 54 (n=4)	50.0 (6.8 to 93.2)			
Month 60 (n=4)	50.0 (6.8 to 93.2)			
Month 66 (n=4)	50.0 (6.8 to 93.2)			
Month 72 (n=3)	33.3 (0.8 to 90.6)			
Month 78 (n=1)	100 (2.5 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity Score Through Month 96: All Periods: Extension Study

End point title	Change From Baseline in Physician's Global Assessment of Disease Activity Score Through Month 96: All Periods: Extension Study

End point description:

PGA of Disease Activity was measured on a VAS ranging from 0 to 10, with 0 = no disease activity and 10= Maximum disease activity, where higher scores indicated greater disease activity. The analysis set included all subjects enrolled in the the extension study. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	98			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n=98)	-4.29 (± 1.87)			
Month 6 (n=96)	-4.51 (± 1.63)			
Month 12 (n=86)	-4.66 (± 1.83)			
Month 18 (n=73)	-4.71 (± 2.10)			
Month 24 (n=63)	-4.67 (± 1.73)			
Month 30 (n=60)	-4.69 (± 1.94)			
Month 36 (n=57)	-4.75 (± 1.72)			
Month 42 (n=53)	-4.71 (± 2.00)			
Month 48 (n=49)	-4.80 (± 1.79)			
Month 54 (n=42)	-5.05 (± 1.82)			
Month 60 (n=39)	-5.19 (± 1.64)			
Month 66 (n=36)	-5.10 (± 1.80)			
Month 72 (n=34)	-5.21 (± 1.81)			
Month 78 (n=30)	-5.15 (± 1.58)			
Month 84 (n=29)	-5.17 (± 1.69)			
Month 90 (n=27)	-5.15 (± 1.67)			
Month 96 (n=23)	-5.11 (± 1.65)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity Score Through Month 96: Withdrawal Period: Extension Study

End point title	Change From Baseline in Physician's Global Assessment of Disease Activity Score Through Month 96: Withdrawal Period: Extension Study

End point description:

PGA of Disease Activity was measured on a VAS ranging from 0 to 10, with 0 = no disease activity and 10= Maximum disease activity, where higher scores indicated greater disease activity. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Data for this endpoint was estimable till Week 78 only. Here, "overall number of participants analyzed" signifies participants evaluable for this outcome measure. Here, "n" signifies subjects evaluable at specific time points. 99999 signifies that standard deviation was not estimable as only 1 subject was evaluated.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78

End point values	Etanercept: Withdrawal Period			
Subject group type	Subject analysis set			
Number of subjects analysed	28			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n= 28)	-5.29 (± 1.98)			
Month 1 (n=24)	-4.92 (± 2.35)			
Month 3 (n=15,)	-4.70 (± 2.40)			
Month 6 (n=12)	-5.50 (± 1.99)			
Month 9 (n=11)	-5.09 (± 2.17)			
Month 12 (n=10)	-5.30 (± 2.14)			
Month 18 (n=10)	-5.15 (± 2.42)			
Month 24 (n=8)	-4.88 (± 2.05)			
Month 30 (n=7)	-4.50 (± 1.89)			
Month 36 (n=7)	-4.50 (± 1.89)			
Month 42 (n=6)	-4.33 (± 2.09)			
Month 48 (n=4)	-5.13 (± 2.10)			
Month 54 (n=3)	-5.33 (± 2.52)			
Month 60 (n=3)	-5.67 (± 2.08)			
Month 66 (n=2)	-6.00 (± 2.83)			
Month 72 (n=2)	-4.50 (± 2.12)			
Month 78 (n=1)	-2.50 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity Score Through Month 96: Re-treatment Period: Extension Study

End point title	Change From Baseline in Physician's Global Assessment of Disease Activity Score Through Month 96: Re-treatment Period: Extension Study

End point description:

PGA of Disease Activity was measured on a VAS ranging from 0 to 10, with 0 = no disease activity and 10= Maximum disease activity, where higher scores indicated greater disease activity. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Data for this endpoint was estimable till Week 78 only. Here, "overall number of participants analyzed" signifies participants evaluable for this outcome measure. Here, "n" signifies subjects evaluable at specific time points. 99999 signifies that standard deviation was not estimable as only 1 subject was evaluated.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n=12)	-0.92 (± 2.33)			
Month 3 (n=13)	-3.73 (± 1.51)			
Month 6 (n=13)	-4.19 (± 1.53)			
Month 9 (n=12)	-4.13 (± 2.05)			
Month 12 (n=11)	-3.82 (± 2.69)			
Month 18 (n=10)	-3.85 (± 2.17)			
Month 24 (n=8)	-3.81 (± 2.55)			
Month 30 (n=9)	-3.94 (± 2.30)			
Month 36 (n=9)	-4.11 (± 2.16)			
Month 42 (n=7)	-4.14 (± 2.53)			
Month 48 (n=6)	-3.58 (± 1.86)			
Month 54 (n=6)	-3.42 (± 1.43)			
Month 60 (n=5)	-2.60 (± 0.74)			
Month 66 (n=4)	-2.63 (± 0.85)			
Month 72 (n=3)	-2.33 (± 0.76)			
Month 78 (n=1)	-3.00 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patient/Parent Global Assessment Score Through Month 96: All Periods: Extension Study

End point title	Change From Baseline in Patient/Parent Global Assessment Score Through Month 96: All Periods: Extension Study

End point description:

Patient/Parent Global Assessment was assessed by the subject's parent using a VAS ranging from 0 to 10, with 0 = very well and 10 = very poor. The analysis set included all subjects enrolled in extension study. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	98			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n=98)	-3.59 (± 2.42)			
Month 6 (n=96)	-3.93 (± 2.31)			

Month 12 (n=85)	-3.79 (± 2.49)			
Month 18 (n=71)	-4.13 (± 2.49)			
Month 24 (n=64)	-4.18 (± 2.60)			
Month 30 (n=61)	-4.38 (± 2.27)			
Month 36 (n=57)	-4.20 (± 2.24)			
Month 42 (n=51)	-4.05 (± 2.85)			
Month 48 (n=49)	-4.37 (± 2.29)			
Month 54 (n=42)	-4.74 (± 2.33)			
Month 60 (n=38)	-4.45 (± 2.57)			
Month 66 (n=36)	-4.54 (± 2.54)			
Month 72 (n=34)	-4.50 (± 2.63)			
Month 78 (n=30)	-4.62 (± 1.87)			
Month 84 (n=29)	-4.57 (± 1.90)			
Month 90 (n=27)	-4.72 (± 2.08)			
Month 96 (n=23)	-4.85 (± 2.11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patient/Parent Global Assessment Score Through Month 96: Withdrawal Period: Extension Study

End point title	Change From Baseline in Patient/Parent Global Assessment Score Through Month 96: Withdrawal Period: Extension Study

End point description:

Patient/Parent Global Assessment was assessed by the subject's parent using a VAS ranging from 0 to 10, with 0 = very well and 10 = very poor. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 96

End point values	Etanercept: Withdrawal Period			
Subject group type	Subject analysis set			
Number of subjects analysed	28			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n= 28)	-4.50 (± 2.45)			
Month 1 (n=24)	-4.38 (± 2.77)			
Month 3 (n=15)	-3.97 (± 2.88)			
Month 6 (n=12)	-5.04 (± 2.58)			
Month 9 (n=10)	-4.65 (± 2.73)			
Month 12 (n=10)	-4.60 (± 2.77)			
Month 18 (n=10)	-4.50 (± 2.84)			
Month 24 (n=8)	-4.63 (± 2.75)			

Month 30 (n=7)	-4.07 (± 2.41)			
Month 36 (n=7)	-4.14 (± 2.66)			
Month 42 (n=6)	-3.83 (± 2.77)			
Month 48 (n=4)	-3.25 (± 3.77)			
Month 54 (n=3)	-4.00 (± 3.77)			
Month 60 (n=3)	-4.00 (± 4.00)			
Month 66 (n=2)	-4.00 (± 5.66)			
Month 72 (n=2)	-4.25 (± 5.30)			
Month 78 (n=1)	-0.50 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patient/Parent Global Assessment Score Through Month 96: Re-treatment Period: Extension Study

End point title	Change From Baseline in Patient/Parent Global Assessment Score Through Month 96: Re-treatment Period: Extension Study

End point description:

Patient/Parent Global Assessment was assessed by the subject's parent using a VAS ranging from 0 to 10, with 0 = very well and 10 = very poor. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 96

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n= 12)	-1.04 (± 2.97)			
Month 3 (n=13)	-2.81 (± 1.95)			
Month 6 (n=13)	-2.73 (± 2.26)			
Month 9 (n=12)	-2.83 (± 2.79)			
Month 12 (n=11)	-2.86 (± 3.03)			
Month 18 (n=10)	-2.65 (± 2.65)			
Month 24 (n=8)	-2.81 (± 2.90)			
Month 30 (n=9)	-2.44 (± 2.86)			
Month 36 (n=9)	-2.83 (± 2.63)			
Month 42 (n=7)	-2.93 (± 3.06)			
Month 48 (n=6)	-2.17 (± 2.36)			
Month 54 (n=6)	-2.33 (± 1.99)			
Month 60 (n=5)	-1.30 (± 1.20)			

Month 66 (n=4)	-1.13 (± 0.95)			
Month 72 (n=3)	-1.50 (± 1.00)			
Month 78 (n=1)	-2.50 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Childhood Health Assessment Questionnaire (CHAQ) Score for Subjects Through Month 96: All Periods: Extension Study

End point title	Change From Baseline in Childhood Health Assessment Questionnaire (CHAQ) Score for Subjects Through Month 96: All Periods: Extension Study

End point description:

Childhood Health Assessment Questionnaire (CHAQ): parent-administered, valid assessment of functional disability, discomfort in pediatrics with rheumatic diseases. Parents report subject's ability to perform activities in 8 domains: dressing, arising, eating, walking,hygiene, reach,grip,common activities distributed in 30 items. Each item scored on 4-point Likert scale: 0=no difficulty;1=some difficulty;2=much difficulty;3=unable to do. Highest score reported for domain is score for that domain. Overall score = sum of domain scores divided by number of domains answered. Total score: 0=no difficulty to 3=extreme difficulty. The analysis set included all subjects enrolled in the extension study. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	80			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n=80)	-0.61 (± 0.60)			
Month 6 (n=74)	-0.66 (± 0.60)			
Month 12 (n=62)	-0.71 (± 0.58)			
Month 18 (n=46)	-0.72 (± 0.56)			
Month 24 (n=37)	-0.81 (± 0.59)			
Month 30 (n=32)	-0.82 (± 0.57)			
Month 36 (n=22)	-0.86 (± 0.60)			
Month 42 (n=21)	-0.81 (± 0.67)			
Month 48 (n=16)	-0.97 (± 0.69)			
Month 54 (n=10)	-1.15 (± 0.75)			
Month 60 (n=8)	-1.33 (± 0.81)			
Month 66 (n=7)	-1.48 (± 0.75)			
Month 72 (n=6)	-1.50 (± 0.76)			
Month 78 (n=5)	-1.40 (± 0.71)			
Month 84 (n=4)	-1.41 (± 0.83)			
Month 90 (n=4)	-1.41 (± 0.83)			

Month 96 (n=2)	-1.13 (± 1.24)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Childhood Health Assessment Questionnaire (CHAQ) Score for Subjects Through Month 96: Withdrawal Period: Extension Study

End point title	Change From Baseline in Childhood Health Assessment Questionnaire (CHAQ) Score for Subjects Through Month 96: Withdrawal Period: Extension Study

End point description:

CHAQ: parent-administered, valid assessment of functional disability, discomfort in pediatrics with rheumatic diseases. Parents report subject's ability to perform activities in 8 domains: dressing, arising, eating, walking, hygiene, reach, grip, common activities distributed in 30 items. Each item scored on 4-point Likert scale: 0=no difficulty;1=some difficulty;2=much difficulty;3=unable to do. Highest score reported for domain is score for that domain. Overall score = sum of domain scores divided by number of domains answered. Total score: 0=no difficulty to 3=extreme difficulty. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Here, "n" signifies subjects evaluable at specific time points. 99999 signifies that standard deviation was not estimable as only 1 subject was evaluated.

End point type	Secondary

End point timeframe:

Baseline through Month 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n= 17)	-0.88 (± 0.77)			
Month 1 (n=15)	-0.81 (± 0.86)			
Month 3 (n=9)	-0.90 (± 0.82)			
Month 6 (n=6)	-1.04 (± 0.95)			
Month 9 (n=6)	-1.04 (± 1.09)			
Month 12 (n=15)	-1.15 (± 1.16)			
Month 18 (n=5)	-1.15 (± 1.16)			
Month 24 (n=1)	-2.13 (± 99999)			
Month 30 (n=1)	-2.13 (± 99999)			
Month 36 (n=1)	-2.13 (± 99999)			
Month 42 (n=1)	-2.13 (± 99999)			
Month 48 (n=1)	-2.13 (± 99999)			

Month 54 (n=1)	-2.13 (± 99999)			
Month 60 (n=1)	-2.13 (± 99999)			
Month 66 (n=1)	-2.13 (± 99999)			
Month 72 (n=1)	-2.13 (± 99999)			
Month 78 (n=1)	-2.13 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Childhood Health Assessment Questionnaire (CHAQ) Score for Subjects Through Month 96: Re-treatment Period: Extension Study

End point title	Change From Baseline in Childhood Health Assessment Questionnaire (CHAQ) Score for Subjects Through Month 96: Re-treatment Period: Extension Study

End point description:

CHAQ: parent-administered, valid assessment of functional disability, discomfort in pediatrics with rheumatic diseases. Parents report subject's ability to perform activities in 8 domains: dressing, arising, eating, walking, hygiene, reach, grip, common activities distributed in 30 items. Each item scored on 4-point Likert scale: 0=no difficulty;1=some difficulty;2=much difficulty;3=unable to do. Highest score reported for domain is score for that domain. Overall score = sum of domain scores divided by number of domains answered. Total score: 0=no difficulty to 3=extreme difficulty. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 96

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	11			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n= 9)	-0.39 (± 0.70)			
Month 3 (n=11)	-0.65 (± 0.66)			
Month 6 (n=10)	-0.66 (± 0.73)			
Month 9 (n=8)	-0.78 (± 0.79)			
Month 12 (n=8)	-0.80 (± 0.78)			
Month 18 (n=8)	-0.78 (± 0.79)			
Month 24 (n=7)	-0.75 (± 0.85)			
Month 30 (n=6)	-0.79 (± 0.92)			
Month 36 (n=6)	-0.88 (± 0.87)			
Month 42 (n=4)	-0.94 (± 1.11)			
Month 48 (n=3)	-0.42 (± 0.62)			

Month 54 (n=3)	-0.42 (± 0.62)			
Month 60 (n=2)	-0.06 (± 0.09)			
Month 66 (n=2)	-0.06 (± 0.09)			
Month 72 (n=1)	-0.13 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Health Assessment Questionnaire (HAQ) Score for Subjects Years Through Month 96: All Periods: Extension Study

End point title	Change From Baseline in Health Assessment Questionnaire (HAQ) Score for Subjects Years Through Month 96: All Periods: Extension Study

End point description:

HAQ: self-reported, valid assessment of functional disability in rheumatoid arthritis. Assessed based on ability of participants to perform daily activities in 8 categories: dressing, arising, eating, walking, reaching, gripping, hygiene, and carrying out daily activities. HAQ score range: 0-3: without any difficulty=0, with some difficulty=1, with much difficulty=2, unable to do=3. HAQ total scores expressed as overall mean score with range 0-3: 0-0.25=normal functioning; 0.25-0.5=mild functional limitation; 0.5-1=moderate functional limitation; more than 1=significant functional limitation. The analysis set included all subjects enrolled in the extension study. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	109			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n=11)	0.10 (± 0.23)			
Month 6 (n=10)	0.09 (± 0.19)			
Month 12 (n=10)	0.10 (± 0.16)			
Month 18 (n=8)	0.09 (± 0.19)			
Month 24 (n=6)	0.13 (± 0.19)			
Month 30 (n=6)	0.15 (± 0.23)			
Month 36 (n=6)	0.17 (± 0.27)			
Month 42 (n=6)	0.13 (± 0.25)			
Month 48 (n=6)	0.17 (± 0.27)			
Month 54 (n=5)	0.13 (± 0.18)			
Month 60 (n=5)	0.18 (± 0.24)			
Month 66 (n=3)	0.33 (± 0.31)			
Month 72 (n=3)	0.29 (± 0.26)			
Month 78 (n=3)	0.13 (± 0.22)			
Month 84 (n=3)	0.25 (± 0.33)			
Month 90 (n=2)	0.13 (± 0.18)			

Month 96 (n=1)	0.63 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Health Assessment Questionnaire (HAQ) Score for Subjects Through Month 96: Withdrawal Period: Extension Study

End point title	Change From Baseline in Health Assessment Questionnaire (HAQ) Score for Subjects Through Month 96: Withdrawal Period: Extension Study

End point description:

Health Assessment Questionnaire (HAQ): self-reported, valid assessment of functional disability in rheumatoid arthritis. Assessed based on ability of participants to perform daily activities in 8 categories: dressing, arising, eating, walking, reaching, gripping, hygiene, and carrying out daily activities. HAQ score range: 0-3: without any difficulty=0, with some difficulty=1, with much difficulty=2, unable to do=3. HAQ total scores expressed as overall mean score with range 0-3: 0-0.25=normal functioning; 0.25-0.5=mild functional limitation; 0.5-1=moderate functional limitation; more than 1=significant functional limitation. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n= 11, 3)	0.00 (± 0.00)			
Month 1 (n=9)	0.00 (± 0.00)			
Month 3 (n=6)	0.02 (± 0.05)			
Month 6 (n=5)	0.03 (± 0.06)			
Month 9 (n=4)	0.00 (± 0.00)			
Month 12 (n=4)	0.00 (± 0.00)			
Month 18 (n=4)	0.00 (± 0.00)			
Month 24 (n=4)	0.00 (± 0.00)			
Month 30 (n=3)	0.04 (± 0.07)			
Month 36 (n=3)	0.00 (± 0.00)			
Month 42 (n=3)	0.00 (± 0.00)			
Month 48 (n=1)	0.00 (± 0.00)			
Month 54 (n=1)	0.00 (± 0.00)			
Month 60 (n=1)	0.00 (± 0.00)			
Month 66 (n=0)	99999 (± 99999)			

Month 72 (n=0)	99999 (± 99999)			
Month 78 (n=0)	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Health Assessment Questionnaire (HAQ) Score for Subjects Through Month 96: Re-treatment Period: Extension Study

End point title	Change From Baseline in Health Assessment Questionnaire (HAQ) Score for Subjects Through Month 96: Re-treatment Period: Extension Study

End point description:

Health Assessment Questionnaire (HAQ): self-reported, valid assessment of functional disability in rheumatoid arthritis. Assessed based on ability of participants to perform daily activities in 8 categories: dressing, arising, eating, walking, reaching, gripping, hygiene, and carrying out daily activities. HAQ score range: 0-3: without any difficulty=0, with some difficulty=1, with much difficulty=2, unable to do=3. HAQ total scores expressed as overall mean score with range 0-3: 0-0.25=normal functioning; 0.25-0.5=mild functional limitation; 0.5-1=moderate functional limitation; more than 1=significant functional limitation. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n=3)	0.79 (± 0.07)			
Month 3 (n=2)	-0.81 (± 0.09)			
Month 6 (n=2)	-0.81 (± 0.09)			
Month 9 (n=3)	-0.42 (± 0.69)			
Month 12 (n=2)	-0.81 (± 0.09)			
Month 18 (n=1)	-0.75 (± 99999)			
Month 24 (n=1)	-0.75 (± 99999)			
Month 30 (n=1)	-0.75 (± 99999)			
Month 36 (n=1)	-0.75 (± 99999)			
Month 42 (n=1)	-0.75 (± 99999)			
Month 48 (n=1)	-0.75 (± 99999)			
Month 54 (n=1)	-0.75 (± 99999)			

Month 60 (n=1)	-0.75 (± 99999)			
Month 66 (n=1)	-0.75 (± 99999)			
Month 72 (n=1)	-0.75 (± 99999)			
Month 78 (n=1)	-0.75 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Joints With Active Arthritis Through Month 96: All Periods: Extension Study

End point title	Change From Baseline in Number of Joints With Active Arthritis Through Month 96: All Periods: Extension Study

End point description:

Joints with active arthritis were defined as joints that were swollen or, in the absence of swelling, joints with limited range of motion accompanied by pain and/or tenderness. The analysis set included all subjects enrolled in the extension study. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: Joints				
arithmetic mean (standard deviation)				
Baseline (n=87)	-6.25 (± 4.89)			
Month 6 (n=25)	-7.00 (± 5.92)			
Month 12 (n=67)	-6.94 (± 5.59)			
Month 18 (n=72)	-6.82 (± 5.39)			
Month 24 (n=65)	-6.48 (± 4.64)			
Month 30 (n=61)	-6.43 (± 4.41)			
Month 36 (n=56)	-6.82 (± 4.46)			
Month 42 (n=52)	-6.98 (± 4.78)			
Month 48 (n=49)	-7.27 (± 4.56)			
Month 54 (n=42)	-7.71 (± 4.93)			
Month 60 (n=39)	-7.74 (± 4.51)			
Month 66 (n=36)	-7.56 (± 4.35)			
Month 72 (n=34)	-7.56 (± 4.24)			
Month 78 (n=30)	-7.40 (± 3.83)			
Month 84 (n=29)	-7.14 (± 3.74)			
Month 90 (n=27)	-7.37 (± 3.69)			
Month 96 (n=23)	-7.17 (± 3.58)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Joints With Active Arthritis Through Month 96: Withdrawal Period: Extension Study

End point title	Change From Baseline in Number of Joints With Active Arthritis Through Month 96: Withdrawal Period: Extension Study

End point description:

Joints with active arthritis were defined as joints that were swollen or, in the absence of swelling, joints with limited range of motion accompanied by pain and/or tenderness. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 96

End point values	Etanercept: Withdrawal Period			
Subject group type	Subject analysis set			
Number of subjects analysed	28			
Units: Joints				
arithmetic mean (standard deviation)				
Baseline (n= 28)	-7.54 (± 4.61)			
Month 1 (n=24)	-6.96 (± 5.38)			
Month 3 (n=15)	-8.53 (± 5.48)			
Month 6 (n=12)	-8.50 (± 4.80)			
Month 9 (n=11)	-8.73 (± 4.96)			
Month 12 (n=10)	-8.70 (± 5.27)			
Month 18 (n=10)	-8.40 (± 5.19)			
Month 24 (n=8)	-8.38 (± 4.69)			
Month 30 (n=7)	-7.00 (± 2.83)			
Month 36 (n=7)	-6.86 (± 3.02)			
Month 42 (n=6)	-7.17 (± 2.99)			
Month 48 (n=4)	-6.75 (± 2.75)			
Month 54 (n=3)	-6.67 (± 3.06)			
Month 60 (n=3)	-7.00 (± 3.00)			
Month 66 (n=2)	-8.50 (± 2.12)			
Month 72 (n=2)	-7.50 (± 2.12)			
Month 78 (n=1)	-5.00 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Joints With Active Arthritis Through Month 96: Re-treatment Period: Extension Study

End point title	Change From Baseline in Number of Joints With Active Arthritis Through Month 96: Re-treatment Period: Extension Study

End point description:

Joints with active arthritis were defined as joints that were swollen or, in the absence of swelling, joints with limited range of motion accompanied by pain and/or tenderness. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 96

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Joints				
arithmetic mean (standard deviation)				
Baseline (n=12)	-1.17 (± 7.25)			
Month 3 (n=13)	-6.31 (± 4.31)			
Month 6 (n=13)	-6.46 (± 4.29)			
Month 9 (n=12)	-6.17 (± 4.73)			
Month 12 (n=11)	-6.18 (± 4.92)			
Month 18 (n=10)	-6.60 (± 4.97)			
Month 24 (n=8)	-5.63 (± 2.62)			
Month 30 (n=9)	-5.33 (± 2.50)			
Month 36 (n=9)	-5.67 (± 2.35)			
Month 42 (n=7)	-5.86 (± 2.54)			
Month 48 (n=6)	-5.33 (± 1.97)			
Month 54 (n=6)	-5.33 (± 1.97)			
Month 60 (n=5)	-4.60 (± 0.89)			
Month 66 (n=4)	-4.75 (± 0.96)			
Month 72 (n=3)	-4.33 (± 0.58)			
Month 78 (n=1)	-5.00 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Joints With Limited Motion Through Month 96: All Periods: Extension Study

End point title	Change From Baseline in Number of Joints With Limited Motion Through Month 96: All Periods: Extension Study

End point description:

Total number of joints with limited range of motion was the number of joints with limited range of motion prorated for missing limited range of motions. It was defined as 69*(total number of joints with score of limited range of motion greater than zero)/number of non-missing limited range of motions. Joint replacement (JR) and not evaluable (NE) were treated as missing. If more than 34 scores of limited range of motion were missing, then the total number of joints with limited range of motion was defined as missing. The analysis set included all subjects enrolled in the extension study. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: Joints				
arithmetic mean (standard deviation)				
Baseline (n=87)	-4.74 (± 4.45)			
Month 6 (n=25)	-4.80 (± 5.39)			
Month 12 (n=67)	-5.51 (± 5.18)			
Month 18 (n=72)	-5.32 (± 5.27)			
Month 24 (n=65)	-5.12 (± 4.83)			
Month 30 (n=61)	-5.03 (± 4.19)			
Month 36 (n=56)	-5.23 (± 4.26)			
Month 42 (n=52)	-5.63 (± 4.69)			
Month 48 (n=49)	-5.90 (± 4.33)			
Month 54 (n=42)	-6.57 (± 4.71)			
Month 60 (n=39)	-6.38 (± 4.02)			
Month 66 (n=36)	-6.64 (± 3.86)			
Month 72 (n=34)	-6.71 (± 4.11)			
Month 78 (n=30)	-6.90 (± 4.15)			
Month 84 (n=29)	-6.45 (± 4.15)			
Month 90 (n=27)	-6.63 (± 3.82)			
Month 96 (n=23)	-6.57 (± 3.72)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Joints With Limited Motion Through

Month 96: Withdrawal Period: Extension Study

End point title	Change From Baseline in Number of Joints With Limited Motion Through Month 96: Withdrawal Period: Extension Study

End point description:

Total number of joints with limited range of motion was the number of joints with limited range of motion prorated for missing limited range of motions. It was defined as 69*(total number of joints with score of limited range of motion greater than zero)/number of non-missing limited range of motions. Joint replacement (JR) and not evaluable (NE) were treated as missing. If more than 34 scores of limited range of motion were missing, then the total number of joints with limited range of motion was defined as missing. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 96

End point values	Etanercept: Withdrawal Period			
Subject group type	Subject analysis set			
Number of subjects analysed	28			
Units: Joints				
arithmetic mean (standard deviation)				
Baseline (n= 28)	-5.50 (± 4.40)			
Month 1 (n=24)	-5.38 (± 4.68)			
Month 3 (n=15)	-5.60 (± 5.15)			
Month 6 (n=12)	-5.67 (± 3.68)			
Month 9 (n=11)	-5.36 (± 3.70)			
Month 12 (n=10)	-5.40 (± 4.01)			
Month 18 (n=10)	-5.10 (± 3.54)			
Month 24 (n=8)	-4.75 (± 3.20)			
Month 30 (n=7)	-4.71 (± 3.45)			
Month 36 (n=7)	-4.71 (± 3.45)			
Month 42 (n=6)	-4.83 (± 3.76)			
Month 48 (n=4)	-3.25 (± 4.03)			
Month 54 (n=3)	-2.00 (± 1.00)			
Month 60 (n=3)	-1.67 (± 1.15)			
Month 66 (n=2)	-2.00 (± 1.41)			
Month 72 (n=2)	-2.00 (± 1.41)			
Month 78 (n=1)	1.00 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Joints With Limited Motion Through Month 96: Re-treatment Period: Extension Study

End point title	Change From Baseline in Number of Joints With Limited Motion Through Month 96: Re-treatment Period: Extension Study

End point description:

Total number of joints with limited range of motion was the number of joints with limited range of motion prorated for missing limited range of motions. It was defined as 69*(total number of joints with score of limited range of motion greater than zero)/number of non-missing limited range of motions. Joint replacement (JR) and not evaluable (NE) were treated as missing. If more than 34 scores of limited range of motion were missing, then the total number of joints with limited range of motion was defined as missing. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 96

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Joints				
arithmetic mean (standard deviation)				
Baseline (n=12)	-1.25 (± 6.41)			
Month 3 (n=13)	-5.15 (± 4.83)			
Month 6 (n=13)	-5.46 (± 4.82)			
Month 9 (n=12)	-4.75 (± 5.59)			
Month 12 (n=11)	-5.45 (± 5.48)			
Month 18 (n=10)	-5.60 (± 5.60)			
Month 24 (n=8)	-3.88 (± 4.45)			
Month 30 (n=9)	-3.78 (± 4.18)			
Month 36 (n=9)	-4.44 (± 3.97)			
Month 42 (n=7)	-4.71 (± 4.39)			
Month 48 (n=6)	-3.83 (± 3.87)			
Month 54 (n=6)	-3.83 (± 3.87)			
Month 60 (n=5)	-2.80 (± 2.86)			
Month 66 (n=4)	-3.00 (± 2.94)			
Month 72 (n=3)	-2.00 (± 2.65)			
Month 78 (n=1)	-1.00 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in C-reactive Protein Through Month 96: All Periods: Extension Study

End point title	Change From Baseline in C-reactive Protein Through Month 96: All Periods: Extension Study

End point description:

The test for CRP is a laboratory measurement for evaluation of an acute phase reactant of inflammation. A decrease in the level of CRP indicates reduction in inflammation and therefore improvement. The analysis set included all subjects enrolled in the extension study. Here, "n" signifies subjects evaluable

at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	92			
Units: mg/Liter (mg/L)				
arithmetic mean (standard deviation)				
Baseline (n=92)	-3.62 (± 12.51)			
Month 6 (n=93)	-3.71 (± 12.20)			
Month 12 (n=82)	-3.37 (± 13.01)			
Month 18 (n=71)	-3.82 (± 15.17)			
Month 24 (n=64)	-4.00 (± 13.89)			
Month 30 (n=61)	-3.89 (± 12.93)			
Month 36 (n=55)	-3.52 (± 14.91)			
Month 42 (n=53)	-1.96 (± 22.18)			
Month 48 (n=49)	-5.01 (± 14.61)			
Month 54 (n=42)	-5.79 (± 15.49)			
Month 60 (n=39)	-3.25 (± 13.28)			
Month 66 (n=36)	-4.39 (± 13.61)			
Month 72 (n=31)	-4.64 (± 13.76)			
Month 78 (n=27)	-4.31 (± 11.17)			
Month 84 (n=28)	-4.52 (± 15.32)			
Month 90 (n=27)	-5.37 (± 15.17)			
Month 96 (n=22)	-0.59 (± 22.63)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in C-reactive Protein Through Month 96: Withdrawal Period: Extension Study

End point title	Change From Baseline in C-reactive Protein Through Month 96:

	Withdrawal Period: Extension Study

End point description:

The test for CRP is a laboratory measurement for evaluation of an acute phase reactant of inflammation. A decrease in the level of CRP indicates reduction in inflammation and therefore improvement. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: mg/Liter (mg/L)				
arithmetic mean (standard deviation)				
Baseline (n= 27)	-6.28 (± 9.22)			
Month 1 (n=22)	-0.99 (± 14.06)			
Month 3 (n=15)	-2.47 (± 6.73)			
Month 6 (n=12)	-3.01 (± 6.89)			
Month 9 (n=11)	-0.27 (± 1.26)			
Month 12 (n=10)	-0.25 (± 1.19)			
Month 18 (n=10)	0.07 (± 2.07)			
Month 24 (n=8)	0.14 (± 1.61)			
Month 30 (n=7)	1.19 (± 2.48)			
Month 36 (n=6)	0.15 (± 1.13)			
Month 42 (n=6)	4.68 (± 10.74)			
Month 48 (n=4)	1.26 (± 4.35)			
Month 54 (n=3)	-0.06 (± 0.82)			
Month 60 (n=3)	0.23 (± 1.15)			
Month 66 (n=2)	-0.10 (± 1.27)			
Month 72 (n=1)	2.80 (± 99999)			
Month 78 (n=1)	-0.40 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in C-reactive Protein Through Month 96: Re-treatment Period: Extension Study

End point title	Change From Baseline in C-reactive Protein Through Month 96: Re-treatment Period: Extension Study

End point description:

The test for CRP is a laboratory measurement for evaluation of an acute phase reactant of inflammation. A decrease in the level of CRP indicates reduction in inflammation and therefore improvement. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 96

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: mg/L				
arithmetic mean (standard deviation)				
Baseline (n=12)	0.32 (± 12.34)			
Month 3 (n=11)	-5.50 (± 11.59)			
Month 6 (n=13)	-5.99 (± 9.03)			
Month 9 (n=12)	-6.42 (± 9.72)			
Month 12 (n=11)	-6.91 (± 9.46)			
Month 18 (n=10)	-6.68 (± 8.88)			
Month 24 (n=8)	-7.79 (± 10.69)			
Month 30 (n=9)	-6.13 (± 11.41)			
Month 36 (n=9)	-5.18 (± 11.87)			
Month 42 (n=7)	2.76 (± 28.99)			
Month 48 (n=6)	0.60 (± 18.68)			
Month 54 (n=6)	0.22 (± 19.92)			
Month 60 (n=5)	20.44 (± 46.78)			
Month 66 (n=4)	-0.10 (± 0.58)			
Month 72 (n=3)	0.57 (± 2.54)			
Month 78 (n=2)	5.30 (± 8.63)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Visual Analogue Scale (VAS) Pain Score Through Month 96: All Periods: Extension Study

End point title	Change From Baseline in Visual Analogue Scale (VAS) Pain Score Through Month 96: All Periods: Extension Study

End point description:

Change from Baseline in VAS pain score; 10-point pain intensity ordinal rating system: 0 = no pain, 1-3 = mild pain, 4-6 = moderate pain, 7-9 = severe pain, 10 = worst possible pain. A higher score indicates greater pain intensity. Change = scores at observation minus score at Baseline. The analysis set included all subjects enrolled in the extension study. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n=78)	-3.94 (± 2.52)			
Month 6 (n=15)	-3.43 (± 2.05)			
Month 12 (n=54)	-4.02 (± 2.52)			
Month 18 (n=64)	-4.24 (± 2.58)			
Month 24 (n=57)	-4.40 (± 2.44)			
Month 30 (n=58)	-4.26 (± 2.50)			
Month 36 (n=56)	-4.03 (± 2.55)			
Month 42 (n=50)	-3.82 (± 3.21)			
Month 48 (n=49)	-4.15 (± 2.55)			
Month 54 (n=42)	-4.51 (± 2.65)			
Month 60 (n=39)	-4.36 (± 2.44)			
Month 66 (n=36)	-4.26 (± 2.67)			
Month 72 (n=34)	-4.19 (± 2.58)			
Month 78 (n=30)	-4.25 (± 2.17)			
Month 84 (n=29)	-4.09 (± 2.26)			
Month 90 (n=27)	-4.20 (± 2.60)			
Month 96 (n=23)	-4.39 (± 2.36)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Visual Analogue Scale (VAS) Pain Score Through Month 96: Withdrawal Period: Extension Study

End point title	Change From Baseline in Visual Analogue Scale (VAS) Pain Score Through Month 96: Withdrawal Period: Extension Study

End point description:

Change from Baseline in VAS pain score; 10-point pain intensity ordinal rating system: 0 = no pain, 1-3 = mild pain, 4-6 = moderate pain, 7-9 = severe pain, 10 = worst possible pain. A higher score indicates greater pain intensity. Change = scores at observation minus score at Baseline. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n= 26)	-4.62 (± 2.69)			
Month 1 (n=22)	-4.75 (± 2.79)			
Month 3 (n=15)	-4.03 (± 2.97)			
Month 6 (n=11)	-5.00 (± 2.66)			
Month 9 (n=11)	-4.36 (± 2.93)			
Month 12 (n=10)	-4.70 (± 2.80)			
Month 18 (n=10)	-4.50 (± 2.89)			
Month 24 (n=8)	-3.81 (± 2.49)			
Month 30 (n=7)	-3.36 (± 3.00)			
Month 36 (n=7)	-4.00 (± 2.93)			
Month 42 (n=6)	-3.67 (± 3.06)			
Month 48 (n=4)	-2.50 (± 3.54)			
Month 54 (n=3)	-3.67 (± 3.25)			
Month 60 (n=3)	-3.50 (± 3.50)			
Month 66 (n=2)	-3.75 (± 4.60)			
Month 72 (n=2)	-3.75 (± 4.60)			
Month 78 (n=1)	-0.50 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Visual Analogue Scale (VAS) Pain Score Through Month 96: Re-treatment Period: Extension Study

End point title	Change From Baseline in Visual Analogue Scale (VAS) Pain Score Through Month 96: Re-treatment Period: Extension Study

End point description:

Change from Baseline in VAS pain score; 10-point pain intensity ordinal rating system: 0 = no pain, 1-3 = mild pain, 4-6 = moderate pain, 7-9 = severe pain, 10 = worst possible pain. A higher score indicates greater pain intensity. Change = scores at observation minus score at Baseline. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Here, "n" signifies subjects evaluable at specific time points. 99999 signifies that standard deviation was not estimable as only 1 subject was evaluated.

End point type	Secondary

End point timeframe:

Baseline, Month 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n=11)	-0.23 (± 3.97)			
Month 3 (n=11)	-2.64 (± 2.68)			
Month 6 (n=13)	-2.65 (± 3.20)			
Month 9 (n=11)	-2.68 (± 2.92)			
Month 12 (n=10)	-3.05 (± 3.72)			
Month 18 (n=10)	-2.25 (± 3.23)			
Month 24 (n=8)	-2.25 (± 3.01)			
Month 30 (n=8)	-2.13 (± 3.06)			
Month 36 (n=7)	-2.29 (± 3.44)			
Month 42 (n=7)	-2.57 (± 3.05)			
Month 48 (n=6)	-1.75 (± 1.89)			
Month 54 (n=6)	-1.75 (± 2.12)			
Month 60 (n=5)	-0.90 (± 0.42)			
Month 66 (n=4)	-0.50 (± 0.71)			
Month 72 (n=3)	-0.83 (± 0.76)			
Month 78 (n=1)	0.00 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Duration of Morning Stiffness Through Month 96: All Periods: Extension Study

End point title	Change From Baseline in Duration of Morning Stiffness Through Month 96: All Periods: Extension Study

End point description:

Duration of morning stiffness was defined as the time elapsed when subject woke up in the morning and was able to resume normal activities without stiffness in minutes (If none was present = 0; If morning stiffness was continuing at the time of assessment or was unusual compared to the recent past, average of duration of stiffness over the past 3 days was reported; If stiffness persisted the entire day, 1440 minutes was recorded). The analysis set included all subjects enrolled in the extension study. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	80			
Units: Minutes				
arithmetic mean (standard deviation)				
Baseline (n=80)	-61.78 (± 90.07)			
Month 6 (n=19)	-52.11 (± 56.63)			
Month 12 (n=57)	-73.33 (± 110.91)			
Month 18 (n=67)	-80.24 (± 108.79)			
Month 24 (n=63)	-72.19 (± 105.84)			
Month 30 (n=59)	-66.36 (± 110.79)			
Month 36 (n=56)	-75.04 (± 112.27)			
Month 42 (n=52)	-73.75 (± 111.59)			
Month 48 (n=49)	-76.22 (± 118.95)			
Month 54 (n=42)	-82.21 (± 124.19)			
Month 60 (n=39)	-89.10 (± 126.62)			
Month 66 (n=36)	-95.56 (± 134.35)			
Month 72 (n=34)	-89.26 (± 148.76)			
Month 78 (n=30)	-91.17 (± 141.86)			
Month 84 (n=29)	-91.83 (± 143.82)			
Month 90 (n=27)	-101.85 (± 140.75)			
Month 96 (n=23)	-99.78 (± 152.26)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Duration of Morning Stiffness Through Month 96: Withdrawal Period: Extension Study

End point title	Change From Baseline in Duration of Morning Stiffness Through Month 96: Withdrawal Period: Extension Study

End point description:

Duration of morning stiffness was defined as the time elapsed when subject woke up in the morning and was able to resume normal activities without stiffness in minutes (If none was present = 0; If morning stiffness was continuing at the time of assessment or was unusual compared to the recent past, average of duration of stiffness over the past 3 days was reported; If stiffness persisted the entire day, 1440 minutes was recorded). The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: Minutes				
arithmetic mean (standard deviation)				
Baseline (n= 27)	-85.74 (± 109.45)			
Month 1 (n=23)	-83.96 (± 119.42)			
Month 3 (n=14)	-71.43 (± 98.85)			
Month 6 (n=12)	-56.67 (± 62.32)			
Month 9 (n=11)	-29.09 (± 26.72)			
Month 12 (n=10)	-32.00 (± 26.27)			
Month 18 (n=10)	-32.00 (± 26.27)			
Month 24 (n=8)	-30.63 (± 29.33)			
Month 30 (n=7)	-30.71 (± 31.68)			
Month 36 (n=7)	-30.71 (± 31.68)			
Month 42 (n=6)	-25.83 (± 31.69)			
Month 48 (n=4)	-31.25 (± 37.50)			
Month 54 (n=6)	-41.67 (± 38.19)			
Month 60 (n=3)	-41.67 (± 38.19)			
Month 66 (n=2)	-25.00 (± 35.36)			
Month 72 (n=2)	-25.00 (± 35.36)			
Month 78 (n=1)	0.00 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Duration of Morning Stiffness Through Month 96: Re-treatment Period: Extension Study

End point title	Change From Baseline in Duration of Morning Stiffness Through Month 96: Re-treatment Period: Extension Study

End point description:

Duration of morning stiffness was defined as the time elapsed when subject woke up in the morning and

was able to resume normal activities without stiffness in minutes (If none was present = 0; If morning stiffness was continuing at the time of assessment or was unusual compared to the recent past, average of duration of stiffness over the past 3 days was reported; If stiffness persisted the entire day, 1440 minutes was recorded). The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 96

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Minutes				
arithmetic mean (standard deviation)				
Baseline (n=13)	-57.92 (± 137.89)			
Month 3 (n=13)	-116.15 (± 138.82)			
Month 6 (n=13)	-107.69 (± 147.90)			
Month 9 (n=12)	-126.67 (± 144.23)			
Month 12 (n=11)	-130.00 (± 151.53)			
Month 18 (n=10)	-111.00 (± 142.53)			
Month 24 (n=8)	-85.63 (± 137.98)			
Month 30 (n=9)	-72.22 (± 142.55)			
Month 36 (n=8)	-89.38 (± 135.24)			
Month 42 (n=7)	-101.43 (± 140.88)			
Month 48 (n=6)	-60.00 (± 94.45)			
Month 54 (n=6)	-60.00 (± 94.45)			
Month 60 (n=5)	-24.00 (± 37.82)			
Month 66 (n=4)	-7.50 (± 9.57)			
Month 72 (n=3)	-10.00 (± 10.00)			
Month 78 (n=1)	-20.00 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Clinically Inactive Disease Through Month 96: All Periods: Extension Study

End point title	Percentage of Subjects With Clinically Inactive Disease Through Month 96: All Periods: Extension Study

End point description:

Inactive disease was defined as no joints with active arthritis, a normal CRP, and a PGA of Disease Activity of 0 on a 21-circle VAS. The analysis set included all subjects enrolled in the extension study. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	109			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 6 (n=68)	11.8 (5.2 to 21.9)			
Month 12 (n=70)	25.7 (16.0 to 37.6)			
Month 18 (n=69)	36.2 (25.0 to 48.7)			
Month 24 (n=62)	24.2 (14.2 to 36.7)			
Month 30 (n=59)	30.5 (19.2 to 43.9)			
Month 36 (n=56)	32.1 (20.3 to 46.0)			
Month 42 (n=53)	32.1 (19.9 to 46.3)			
Month 48 (n=49)	28.6 (16.6 to 43.3)			
Month 54 (n=42)	33.3 (19.6 to 49.5)			
Month 60 (n=39)	30.8 (17.0 to 47.6)			
Month 66 (n=36)	25.0 (12.1 to 42.2)			
Month 72 (n=33)	12.1 (3.4 to 28.2)			
Month 78 (n=30)	23.3 (9.9 to 42.3)			
Month 84 (n=29)	27.6 (12.7 to 47.2)			
Month 90 (n=27)	25.9 (11.1 to 46.3)			
Month 96 (n=23)	26.1 (10.2 to 48.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Clinically Inactive Disease Through Month 96: Withdrawal Period: Extension Study

End point title	Percentage of Subjects With Clinically Inactive Disease Through Month 96: Withdrawal Period: Extension Study

End point description:

Inactive disease was defined as no joints with active arthritis, a normal CRP, and a PGA of Disease Activity of 0 on a 21-circle VAS. The WAS included those subjects who entered the withdrawal period. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 1 (n=22)	54.5 (32.2 to 75.6)			
Month 3 (n=15)	66.7 (38.4 to 88.2)			
Month 6 (n=12)	66.7 (34.9 to 90.1)			
Month 9 (n=11)	81.8 (48.2 to 97.7)			
Month 12 (n=10)	80.0 (44.4 to 97.5)			
Month 18 (n=10)	80.0 (44.4 to 97.5)			
Month 24 (n=8)	87.5 (47.3 to 99.7)			
Month 30 (n=7)	71.4 (29.0 to 96.3)			
Month 36 (n=6)	83.3 (35.9 to 99.6)			
Month 42 (n=6)	50.0 (11.8 to 88.2)			
Month 48 (n=4)	50.0 (6.8 to 93.2)			
Month 54 (n=3)	66.7 (9.4 to 99.2)			
Month 60 (n=3)	100 (29.2 to 100)			
Month 66 (n=2)	100 (15.8 to 100)			
Month 72 (n=2)	0.0 (0.0 to 84.2)			
Month 78 (n=1)	0.0 (0.0 to 97.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Clinically Inactive Disease Through Month 96: Re-treatment Period: Extension Study

End point title	Percentage of Subjects With Clinically Inactive Disease Through Month 96: Re-treatment Period: Extension Study

End point description:

Inactive disease was defined as no joints with active arthritis, a normal CRP, and a PGA of Disease Activity of 0 on a 21-circle VAS. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Percentage of subjects				
number (confidence interval 95%)				
Month 3 (n=13)	23.1 (5.0 to 53.8)			
Month 6 (n=13)	46.2 (19.2 to 74.9)			
Month 9 (n=12)	33.3 (9.9 to 65.1)			
Month 12 (n=11)	45.5 (16.7 to 76.6)			
Month 18 (n=10)	50.0 (18.7 to 81.3)			
Month 24 (n=8)	62.5 (24.5 to 91.5)			
Month 30 (n=9)	33.3 (7.5 to 70.1)			
Month 36 (n=9)	55.6 (21.2 to 86.3)			
Month 42 (n=7)	28.6 (3.7 to 71.0)			
Month 48 (n=6)	16.7 (0.4 to 64.1)			
Month 54 (n=6)	33.3 (4.3 to 77.7)			
Month 60 (n=5)	40.0 (5.3 to 85.3)			
Month 66 (n=4)	50.0 (6.8 to 93.2)			
Month 72 (n=3)	33.3 (0.8 to 90.6)			
Month 78 (n=2)	50.0 (1.3 to 98.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Juvenile Arthritis Disease Activity Score (JADAS) Through Month 96: All Periods: Extension Study

End point title	Change From Baseline in Juvenile Arthritis Disease Activity Score (JADAS) Through Month 96: All Periods: Extension Study

End point description:

JADAS score was derived from four components; 1) Physician global assessment of disease activity (assessed on a VAS of 0 [no activity] to 10 [maximum activity]), 2) Parent/legal guardian/subject global assessment of overall well-being (assessed on a VAS of 0 [very well] to 10 [very poor]), 3) Number of joints with active disease(defined as joint with swelling or, in absence of swelling, limited range of motion accompanied by either pain on motion or tenderness), 4) CRP (measured in milligram per liter [mg/L] and value normalized to 0 to 10 scale). A higher score indicates more disease activity. The analysis set included all subjects enrolled in the extension study. Here, "overall number of participants analyzed" signifies participants evaluable for this outcome measure. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	80			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n=73)	-14.69 (± 7.61)			
Month 6 (n=23)	-15.00 (± 8.08)			
Month 12 (n=57)	-15.09 (± 8.01)			
Month 18 (n=61)	-15.83 (± 9.11)			
Month 24 (n=59)	-15.73 (± 7.84)			
Month 30 (n=57)	-15.54 (± 7.51)			
Month 36 (n=50)	-15.89 (± 7.40)			
Month 42 (n=47)	-16.23 (± 8.42)			
Month 48 (n=46)	-16.65 (± 7.70)			
Month 54 (n=40)	-17.68 (± 8.15)			
Month 60 (n=36)	-17.26 (± 6.90)			
Month 66 (n=34)	-17.19 (± 6.79)			
Month 72 (n=30)	-17.48 (± 6.77)			
Month 78 (n=25)	-17.13 (± 4.66)			
Month 84 (n=26)	-16.68 (± 4.81)			

Month 90 (n=25)	-17.18 (± 4.51)			
Month 96 (n=21)	-16.92 (± 4.75)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Juvenile Arthritis Disease Activity Score (JADAS) Through Month 96: Withdrawal Period: Extension Study

End point title	Change From Baseline in Juvenile Arthritis Disease Activity Score (JADAS) Through Month 96: Withdrawal Period: Extension Study

End point description:

JADAS score was derived from four components; 1) Physician global assessment of disease activity (assessed on a VAS of 0 [no activity] to 10 [maximum activity]), 2) Parent/legal guardian/subject global assessment of overall well-being (assessed on a VAS of 0 [very well] to 10 [very poor]), 3) Number of joints with active disease(defined as joint with swelling or, in absence of swelling, limited range of motion accompanied by either pain on motion or tenderness), 4) CRP (measured in milligram per liter [mg/L] and value normalized to 0 to 10 scale). A higher score indicates more disease activity. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Here, "n" signifies subjects evaluable at specific time points. Here, 9999 signifies that mean and standard deviation could not be calculated as there were no participants evaluable.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	24			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n= 24)	-18.24 (± 7.51)			
Month 1 (n=19)	-16.66 (± 8.96)			
Month 3 (n=14)	-17.90 (± 9.04)			
Month 6 (n=10)	-20.41 (± 8.34)			
Month 9 (n=8)	-20.25 (± 9.45)			
Month 12 (n=8)	-20.19 (± 9.36)			
Month 18 (n=8)	-19.44 (± 9.83)			
Month 24 (n=6)	-19.42 (± 9.18)			
Month 30 (n=5)	-16.60 (± 6.32)			
Month 36 (n=4)	-15.50 (± 7.33)			

Month 42 (n=5)	-16.10 (± 6.58)			
Month 48 (n=3)	-17.83 (± 7.18)			
Month 54 (n=2)	-19.25 (± 9.55)			
Month 60 (n=2)	-19.50 (± 9.19)			
Month 66 (n=1)	-26.00 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Juvenile Arthritis Disease Activity Score (JADAS) Through Month 96: Re-treatment Period: Extension Study

End point title	Change From Baseline in Juvenile Arthritis Disease Activity Score (JADAS) Through Month 96: Re-treatment Period: Extension Study

End point description:

JADAS score was derived from four components; 1) Physician global assessment of disease activity (assessed on a VAS of 0 [no activity] to 10 [maximum activity]), 2) Parent/legal guardian/subject global assessment of overall well-being (assessed on a VAS of 0 [very well] to 10 [very poor]), 3) Number of joints with active disease(defined as joint with swelling or, in absence of swelling, limited range of motion accompanied by either pain on motion or tenderness), 4) CRP (measured in milligram per liter [mg/L] and value normalized to 0 to 10 scale). A higher score indicates more disease activity. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Here, "n" signifies subjects evaluable at specific time points. Data for this endpoint was estimable till Week 78 only.99999 signifies that standard deviation was not estimable as only 1 subject was evaluated.

End point type	Secondary

End point timeframe:

Baseline, Month 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78

End point values	Etanercept: Re-treatment Period			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n=12)	-3.18 (± 9.69)			
Month 3 (n=11)	-13.59 (± 6.06)			
Month 6 (n=13)	-13.80 (± 6.68)			
Month 9 (n=11)	-14.39 (± 7.98)			
Month 12 (n=11)	-13.26 (± 9.31)			
Month 18 (n=10)	-13.51 (± 8.78)			

Month 24 (n=8)	-12.68 (± 8.45)			
Month 30 (n=9)	-12.04 (± 7.89)			
Month 36 (n=9)	-12.90 (± 7.47)			
Month 42 (n=7)	-12.45 (± 9.24)			
Month 48 (n=6)	-10.85 (± 6.66)			
Month 54 (n=6)	-10.85 (± 5.96)			
Month 60 (n=5)	-6.82 (± 4.33)			
Month 66 (n=4)	-8.50 (± 2.12)			
Month 72 (n=3)	-8.17 (± 2.25)			
Month 78 (n=1)	-10.50 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Overall Back Pain Through Month 96: Enthesitis-Related Arthritis (ERA): All Periods: Extension Study

End point title	Change From Baseline in Overall Back Pain Through Month 96: Enthesitis-Related Arthritis (ERA): All Periods: Extension Study

End point description:

Overall back pain assessed by subject's parent using a 100 millimeter (mm) VAS with 0 mm= no pain and 100 mm= most severe pain. The analysis set included all subjects enrolled in the extension study. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Enthesitis-Related Arthritis			
Subject group type	Subject analysis set			
Number of subjects analysed	26			
Units: millimeter (mm)				
arithmetic mean (standard deviation)				
Baseline (n=26)	-16.99 (± 22.80)			
Month 12 (n=21)	-19.88 (± 27.66)			
Month 18 (n=25)	-21.66 (± 28.26)			
Month 24 (n=22)	-20.34 (± 30.98)			
Month 30 (n=20)	-20.08 (± 31.57)			

Month 36 (n=20)	-21.50 (± 28.70)			
Month 42 (n=19)	-21.69 (± 31.79)			
Month 48 (n=18)	-20.37 (± 34.06)			
Month 54 (n=14)	-20.98 (± 34.18)			
Month 60 (n=12)	-20.14 (± 25.00)			
Month 66 (n=11)	-18.15 (± 26.87)			
Month 72 (n=11)	-18.52 (± 24.80)			
Month 78 (n=10)	-16.07 (± 27.50)			
Month 84 (n=10)	-17.07 (± 28.19)			
Month 90 (n=10)	-17.57 (± 29.17)			
Month 96 (n=8)	-20.84 (± 30.08)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Overall Back Pain Through Month 96: Enthesitis-Related Arthritis (ERA): Withdrawal Period: Extension Study

End point title	Change From Baseline in Overall Back Pain Through Month 96: Enthesitis-Related Arthritis (ERA): Withdrawal Period: Extension Study

End point description:

Overall back pain assessed by subject's parent using a 100 millimeter (mm) VAS with 0 mm= no pain and 100 mm= most severe pain. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Here, "n" signifies subjects evaluable at specific time points. Data for this endpoint was estimable till Week 42 only.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42

End point values	Enthesitis-Related Arthritis			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: mm				
arithmetic mean (standard deviation)				
Baseline (n=8)	-15.88 (± 25.35)			
Month 1 (n=7)	-18.13 (± 26.75)			

Month 3 (n=4)	-27.48 (± 33.22)			
Month 6 (n=3)	-35.21 (± 33.07)			
Month 9 (n=2)	-30.50 (± 51.62)			
Month 12 (n=2)	-32.00 (± 49.50)			
Month 18 (n=2)	-33.50 (± 47.38)			
Month 24 (n=2)	-33.50 (± 47.38)			
Month 30 (n=2)	-14.00 (± 74.95)			
Month 36 (n=2)	-29.00 (± 53.74)			
Month 42 (n=2)	-34.00 (± 46.67)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Overall Back Pain Through Month 96: Enthesitis-Related Arthritis (ERA): Re-treatment Period: Extension Study

End point title	Change From Baseline in Overall Back Pain Through Month 96: Enthesitis-Related Arthritis (ERA): Re-treatment Period: Extension Study

End point description:

Overall back pain assessed by subject's parent using a 100 millimeter (mm) VAS with 0 mm= no pain and 100 mm= most severe pain. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Here, "n" signifies subjects evaluable at specific time points. Data for this endpoint was estimable till Week 60 only. 99999 signifies that standard deviation was not estimable as only 1 subject was evaluated.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60

End point values	Enthesitis-Related Arthritis			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: mm				
arithmetic mean (standard deviation)				
Baseline (n=1)	-16.00 (± 99999)			
Month 3 (n=2)	-21.00 (± 7.07)			
Month 6 (n=2)	-29.00 (± 18.38)			
Month 9 (n=2)	-24.50 (± 12.02)			

Month 12 (n=2)	-23.50 (± 10.61)			
Month 18 (n=1)	-31.00 (± 99999)			
Month 30 (n=1)	-13.00 (± 99999)			
Month 36 (n=1)	-22.00 (± 99999)			
Month 42 (n=1)	-26.00 (± 99999)			
Month 46 (n=1)	-21.00 (± 99999)			
Month 54 (n=1)	-26.00 (± 99999)			
Month 60 (n=1)	-14.00 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Nocturnal Back Pain Through Month 96: Enthesitis-Related Arthritis (ERA): All Periods: Extension Study

End point title	Change From Baseline in Nocturnal Back Pain Through Month 96: Enthesitis-Related Arthritis (ERA): All Periods: Extension Study

End point description:

Nocturnal back pain assessed by subject's parent using a 100 mm VAS with 0 mm = no pain and 100 mm = most severe pain. The analysis set included all subjects enrolled in the extension study. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Enthesitis-Related Arthritis			
Subject group type	Subject analysis set			
Number of subjects analysed	26			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n=26)	-8.84 (± 21.37)			
Month 12 (n=21)	-17.41 (± 29.79)			
Month 18 (n=25)	-14.99 (± 28.13)			
Month 24 (n=22)	-16.90 (± 29.53)			
Month 30 (n=20)	-18.09 (± 31.21)			
Month 36 (n=20)	-17.31 (± 29.73)			

Month 42 (n=19)	-19.23 (± 30.56)			
Month 48 (n=18)	-19.16 (± 31.13)			
Month 54 (n=14)	-23.78 (± 33.66)			
Month 60 (n=12)	-19.83 (± 30.43)			
Month 66 (n=11)	-19.99 (± 29.90)			
Month 72 (n=11)	-16.45 (± 29.24)			
Month 78 (n=10)	-15.89 (± 30.10)			
Month 84 (n=10)	-18.49 (± 34.10)			
Month 90 (n=10)	-17.39 (± 37.42)			
Month 96 (n=8)	-22.49 (± 37.77)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Nocturnal Back Pain Through Month 96: Enthesitis-Related Arthritis (ERA): Withdrawal Period: Extension Study

End point title	Change From Baseline in Nocturnal Back Pain Through Month 96: Enthesitis-Related Arthritis (ERA): Withdrawal Period: Extension Study

End point description:

Nocturnal back pain assessed by subject's parent using a 100 mm VAS with 0 mm = no pain and 100 mm = most severe pain. The WAS included those subjects who entered the withdrawal period. Only data collected in the withdrawal period was included. Here, "n" signifies subjects evaluable at specific time points. Data for this endpoint was estimable till Week 42 only.

End point type	Secondary

End point timeframe:

Baseline, Month 1, 3, 6, 9, 12, 18, 24, 30, 36, 42

End point values	Enthesitis-Related Arthritis			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: mm				
arithmetic mean (standard deviation)				
Baseline (n=8)	-1.38 (± 3.16)			
Month 1 (n=7)	-1.28 (± 3.45)			
Month 3 (n=4)	0.02 (± 0.03)			
Month 6 (n=3)	0.04 (± 1.06)			
Month 9 (n=2)	0.50 (± 0.71)			
Month 12 (n=2)	-0.50 (± 0.71)			

Month 18 (n=2)	0.00 (± 0.00)			
Month 24 (n=2)	0.00 (± 0.00)			
Month 30 (n=2)	11.50 (± 16.26)			
Month 36 (n=2)	0.00 (± 0.00)			
Month 42 (n=2)	0.00 (± 0.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Nocturnal Back Pain Through Month 96: Enthesitis-Related Arthritis (ERA): Re-treatment Period: Extension Study

End point title	Change From Baseline in Nocturnal Back Pain Through Month 96: Enthesitis-Related Arthritis (ERA): Re-treatment Period: Extension Study

End point description:

Nocturnal back pain assessed by subject's parent using a 100 mm VAS with 0 mm = no pain and 100 mm = most severe pain. The RTAS included those subjects who entered the re-treatment period. Only data collected in the re-treatment period was included. Here, "n" signifies subjects evaluable at specific time points. Data for this endpoint was estimable till Week 60 only.

End point type	Secondary

End point timeframe:

Baseline, Month 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60

End point values	Enthesitis-Related Arthritis			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: mm				
arithmetic mean (standard deviation)				
Baseline (n=1)	-9.00 (± 99999)			
Month 3 (n=2)	-3.00 (± 8.49)			
Month 6 (n=2)	-6.00 (± 4.24)			
Month 9 (n=2)	-0.50 (± 12.02)			
Month 12 (n=2)	0.00 (± 12.73)			
Month 18 (n=1)	4.00 (± 99999)			
Month 30 (n=1)	14.00 (± 99999)			
Month 36 (n=1)	17.00 (± 99999)			
Month 42 (n=1)	7.00 (± 99999)			
Month 48 (n=1)	10.00 (± 99999)			
Month 54 (n=1)	5.00 (± 99999)			
Month 60 (n=1)	38.00 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bath Ankylosing Spondylitis Metrology Index (BASMI) Score Through Month 96: Enthesitis-Related Arthritis (ERA): All Periods: Extension Study

End point title	Bath Ankylosing Spondylitis Metrology Index (BASMI) Score Through Month 96: Enthesitis-Related Arthritis (ERA): All Periods: Extension Study

End point description:

Bath Ankylosing Spondylitis Metrology Index (BASMI) is an objective measure of spinal mobility. The BASMI score is composed of 5 measures: cervical rotation, intermalleolar distance, modified Schober's test, lateral flexion and tragus to wall distance. Each measure was scored 0-2 (0=normal mobility, 2=severe reduction) to give a final score ranging 0 to 10. The analysis set included all subjects enrolled in extension study. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Enthesitis-Related Arthritis			
Subject group type	Subject analysis set			
Number of subjects analysed	24			
Units: Units on scale				
arithmetic mean (standard deviation)				
Month 12 (n=20)	0.39 (± 0.64)			
Month 18 (n=24)	0.21 (± 0.51)			
Month 24 (n=22)	0.23 (± 0.53)			
Month 30 (n=20)	0.40 (± 0.68)			
Month 36 (n=20)	0.30 (± 0.66)			
Month 42 (n=18)	0.17 (± 0.51)			
Month 48 (n=18)	0.28 (± 0.67)			
Month 54 (n=14)	0.21 (± 0.58)			
Month 60 (n=12)	0.17 (± 0.39)			
Month 66 (n=11)	0.09 (± 0.30)			
Month 72 (n=11)	0.09 (± 0.30)			
Month 78 (n=10)	0.10 (± 0.32)			
Month 84 (n=10)	0.10 (± 0.32)			
Month 90 (n=10)	0.10 (± 0.32)			
Month 96 (n=8)	0.00 (± 0.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Percentage Body Surface Area Through Month 96: Psoriatic Arthritis (PsA): All Periods: Extension Study

End point title	Change From Baseline in Percentage Body Surface Area Through Month 96: Psoriatic Arthritis (PsA): All Periods: Extension Study

End point description:

Percentage of body surface area affected by psoriasis was estimated using the palm method: one of the subject's palm to proximal interphalangeal and thumb= 1 percent (%) of BSA. Regions of the body were assigned specific number of palms with percentage [Head and neck= 10% (10 palms), upper extremities= 20% (20 palms), Trunk (axillae and groin)= 30% (30 palms), lower extremities (buttocks)= 40% (40 palms)]. The total BSA affected was the summation of individual regions affected. The FAS for active treatment period included all subjects in the parent study who received at least one dose of investigational product regardless of whether they received any investigational product during the extension study. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Month 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78

End point values	Psoriatic Arthritis (PsA)			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: Percentage of body surface area				
arithmetic mean (standard deviation)				
Baseline (n=19)	-7.74 (± 12.52)			
Month 6 (n=10)	-5.45 (± 10.36)			
Month 12 (n=15)	-10.07 (± 13.96)			
Month 18 (n=15)	-9.82 (± 12.55)			
Month 24 (n=13)	-11.85 (± 13.71)			
Month 30 (n=14)	-10.95 (± 14.42)			
Month 36 (n=13)	-10.38 (± 15.93)			
Month 42 (n=14)	-11.18 (± 14.21)			
Month 48 (n=12)	-11.81 (± 14.06)			
Month 54 (n=11)	-12.45 (± 14.34)			
Month 60 (n=11)	-12.09 (± 13.66)			
Month 66 (n=10)	-10.88 (± 13.38)			
Month 72 (n=9)	-8.88 (± 19.95)			
Month 78 (n=8)	-13.39 (± 14.64)			

Month 84 (n=8)	-13.50 (± 14.93)			
Month 90 (n=6)	-16.83 (± 15.83)			
Month 96 (n=5)	-15.80 (± 17.47)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Physician's Global Assessment (PGA) of Psoriasis Score Through Month 96: Psoriatic Arthritis (PsA): All Periods: Extension Study

End point title	Change From Baseline in Physician's Global Assessment (PGA) of Psoriasis Score Through Month 96: Psoriatic Arthritis (PsA): All Periods: Extension Study

End point description:

PGA of Psoriasis assessed the amount of induration, erythema, and scaling averaged over all psoriatic lesions on a scale of 0 to 5. 0 (no psoriasis) to 5 (severe disease). 'Clear' and "Almost clear' includes all participants who were scored as a 0 or 1. The analysis set included all subjects enrolled in the extension study.

End point type	Secondary

End point timeframe:

Baseline, Month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

End point values	Psoriatic Arthritis (PsA)			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: Units on scale				
arithmetic mean (standard deviation)				
Baseline (n=19)	-1.16 (± 1.26)			
Month 6 (n=9)	-1.33 (± 1.41)			
Month 12 (n=15)	-1.33 (± 1.23)			
Month 18 (n=15)	-1.20 (± 1.26)			
Month 24 (n=13)	-1.54 (± 1.27)			
Month 30 (n=14)	-1.07 (± 1.49)			
Month 36 (n=14)	-1.21 (± 1.12)			
Month 42 (n=14)	-1.50 (± 1.22)			
Month 48 (n=12)	-1.42 (± 1.08)			
Month 54 (n=11)	-1.18 (± 1.33)			
Month 60 (n=11)	-1.18 (± 1.17)			
Month 66 (n=10)	-1.20 (± 0.92)			
Month 72 (n=9)	-1.11 (± 1.05)			
Month 78 (n=8)	-1.13 (± 1.13)			
Month 84 (n=8)	-1.50 (± 1.07)			
Month 90 (n=6)	-1.50 (± 1.05)			
Month 96 (n=5)	-1.80 (± 1.10)			

Statistical analyses

No statistical analyses for this end point

Secondary: All Cause Mortality: All Periods: Extension Study

End point title	All Cause Mortality: All Periods: Extension Study

End point description:

The considered event was death due to any cause from baseline to the end of the study. The full analysis set for extension study included all subjects enrolled in the extension study.

End point type	Secondary

End point timeframe:

Baseline upto Month 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	109			
Units: Subjects	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Prior Non-study Medication: All Periods: Extension Study

End point title	Number of Subjects With Prior Non-study Medication: All Periods: Extension Study

End point description:

Prior non-study medications were defined as any non-study medications taken before the first dose of investigational product taken at the start of the study. The analysis set included all subjects enrolled in extension study.

End point type	Secondary

End point timeframe:

Baseline up to Month 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	109			
Units: Subjects				
Anti-infective	2			
Corticosteroids	5			
Oral corticosteroids	5			
Parenteral corticosteroid	99999			
Disease-modifying antirheumatic drugs	57			
Oral Non-steroidal anti-inflammatory medication	13			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Concomitant Non-study Medication: All Periods: Extension Study

End point title	Number of Subjects With Concomitant Non-study Medication: All Periods: Extension Study

End point description:

Concomitant non-study medications were defined as any non-study medications taken during the treatment period. The analysis set included all subjects enrolled the extension study.

End point type	Secondary

End point timeframe:

Baseline up to Month 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	109			
Units: Subjects				
Anti-infective medications	62			
Corticosteroids	29			
Oral corticosteroids	16			
Parenteral corticosteroid	12			
Disease-modifying antirheumatic drugs	64			
Non-steroidal anti-inflammatory drugs	51			
Oral Non-steroidal anti-inflammatory drugs	48			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With After Non-study Medication: All Periods:

Extension Study

End point title	Number of Subjects With After Non-study Medication: All Periods: Extension Study

End point description:

After non-study medications referred to any non-study medications taken after the last dose of the investigational product. The analysis set included all subjects enrolled in the extension study.

End point type	Secondary

End point timeframe:

Baseline up to Month 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	109			
Units: Subjects				
Anti-infectives	7			
Corticosteroids	6			
Oral corticosteroids	3			
Parenteral corticosteroid	1			
Disease-modifying antirheumatic drugs	48			
Non-steroidal anti-inflammatory drugs	16			
Oral Non-steroidal anti-inflammatory drugs	16			

Statistical analyses

No statistical analyses for this end point

Secondary: Exposure Time: All Periods: Extension Study

End point title	Exposure Time: All Periods: Extension Study

End point description:

The exposure time (years) to etanercept was calculated for each subject each period using (the last dose date – the first dose date + 1)/365.25. If the gap was less than 28 days between two etanercept treatment periods, the cumulative exposure included the gap. Else, the gap was excluded from the cumulative exposure. The analysis set included all subjects enrolled in the extension study.

End point type	Secondary

End point timeframe:

First dose to the last dose

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	99			
Units: Years				
arithmetic mean (standard deviation)	244.79 (± 147.71)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Total CHAQ Score Improvement of >0.188 From Baseline of 1014:All Periods: Extension Study

End point title	Percentage of Participants With Total CHAQ Score Improvement of >0.188 From Baseline of 1014:All Periods: Extension Study

End point description:

Childhood Health Assessment Questionnaire (CHAQ): parent-administered, valid assessment of functional disability, discomfort in pediatrics with rheumatic diseases. Parents report subject's ability to perform activities in 8 domains: dressing, arising, eating, walking,hygiene, each,grip,common activities distributed in total of 30 items.Each item is scored on 4-point Likert scale: 0=no difficulty;1=some difficulty;2=much difficulty;3=unable to do. Highest score reported for domain is score for that domain. Overall score = sum of domain scores divided by number of domains answered. Total score: 0=no difficulty to 3=extreme difficulty. Here, "n" signifies subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline of parent study through Month 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	80			
Units: Percentage of Subjects				
number (confidence interval 95%)				
Baseline (n=80)	68.8 (57.4 to 78.7)			
Month 6 (n=74)	73.0 (61.4 to 82.6)			
Month 12 (n=62)	79.0 (66.8 to 88.3)			
Month 18 (n=46)	78.3 (63.6 to 89.1)			
Month 24 (n=37)	86.5 (71.2 to 95.5)			
Month 30 (n=32)	90.6 (75.0 to 98.0)			
Month 36 (n=22)	90.9 (70.8 to 98.9)			
Month 42 (n=21)	95.2 (76.2 to 99.9)			
Month 48 (n=16)	93.8 (69.8 to 99.8)			
Month 54 (n=10)	100.0 (69.2 to 100.0)			
Month 60 (n=8)	100.0 (63.1 to 100.0)			

Month 66 (n=7)	100.0 (59.0 to 100.0)			
Month 72 (n=6)	100.0 (54.1 to 100.0)			
Month 78 (n=5)	100.0 (47.8 to 100.0)			
Month 84 (n=4)	100.0 (39.8 to 100.0)			
Month 90 (n=4)	100.0 (39.8 to 100.0)			
Month 96 (n=2)	100.0 (15.8 to 100.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Vital Signs Abnormalities: All Periods: Parent and Extension Study

End point title	Number of Subjects With Vital Signs Abnormalities: All Periods: Parent and Extension Study

End point description:

Vital signs assessment included temperature, pulse, systolic and diastolic blood pressure. Pulse rate was obtained with subject in the seated position, after having sat calmly for at least 5 minutes. Clinical significance of vital signs was determined at the investigator's discretion. The FAS included all subjects in the parent study who received at least 1 dose of investigational product regardless of whether they received any investigational product during the extension study.

End point type	Secondary

End point timeframe:

Baseline up to 96 months

End point values	All Periods (Parent and Extension Study)			
Subject group type	Subject analysis set			
Number of subjects analysed	99			
Units: Subjects				
Pulse (low)	1			
Systolic blood pressure (high)	14			
Diastolic blood pressure (low)	4			
Diastolic blood pressure (high)	2			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Screening up to Month 96

Adverse event reporting additional description:

The same event may appear as both an AE and a SAE. However, what is presented are distinct events. An event may be categorized as serious in one subject and as non-serious in another subject, or one subject may have experienced both a serious and non-serious event during the study. AEs and SAEs were analysed for full analysis set.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	v23.1

Reporting groups

Reporting group title	Etanercept

Reporting group description:

Etanercept was administered 0.8 mg/kg up to a maximum dose of 50 mg once weekly subcutaneously for 96 months.

Serious adverse events	Etanercept		
Total subjects affected by serious adverse events			
subjects affected / exposed	22 / 109 (20.18%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Vascular disorders			
Varicose vein			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Knee operation			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hodgkin's disease			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Depression			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Attention deficit hyperactivity disorder			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Varicocele			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meniscus injury			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fractured coccyx			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Facial bones fracture			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to	0 / 1		

treatment / all			
deaths causally related to treatment / all	0 / 0		
Multiple fractures			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Radius fracture			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Psychomotor hyperactivity			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Iridocyclitis			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Uveitis			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	2 / 109 (1.83%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Intestinal perforation			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			

Renal colic				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Psoriasis				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Synovitis				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Appendicitis				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Anal abscess				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dengue fever				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences causally related to treatment / all	1 / 1			

deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Etanercept		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	85 / 109 (77.98%)		
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Surgical and medical procedures			
Wisdom teeth removal			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Tonsillectomy			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Uterine leiomyoma			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
General disorders and administration site conditions			

Pyrexia subjects affected / exposed occurrences (all)	6 / 109 (5.50%) 9		
Injection site reaction subjects affected / exposed occurrences (all)	6 / 109 (5.50%) 7		
Chest pain subjects affected / exposed occurrences (all)	2 / 109 (1.83%) 2		
Peripheral swelling subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		
Influenza like illness subjects affected / exposed occurrences (all)	2 / 109 (1.83%) 5		
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	2 / 109 (1.83%) 2		
Vaginal discharge subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		
Ovarian cyst subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		
Injury, poisoning and procedural complications Animal bite subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		
Chillblains subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		

Contusion				
subjects affected / exposed	4 / 109 (3.67%)			
occurrences (all)	4			
Facial bones fracture				
subjects affected / exposed	2 / 109 (1.83%)			
occurrences (all)	2			
Fibula fracture				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Foot fracture				
subjects affected / exposed	2 / 109 (1.83%)			
occurrences (all)	2			
Hand fracture				
subjects affected / exposed	2 / 109 (1.83%)			
occurrences (all)	2			
Head injury				
subjects affected / exposed	2 / 109 (1.83%)			
occurrences (all)	2			
Joint dislocation				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Joint injury				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Ligament sprain				
subjects affected / exposed	4 / 109 (3.67%)			
occurrences (all)	7			
Limb injury				
subjects affected / exposed	2 / 109 (1.83%)			
occurrences (all)	2			
Post-traumatic neck syndrome				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Radius fracture				
subjects affected / exposed	3 / 109 (2.75%)			
occurrences (all)	4			

Skin laceration			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	2		
Patella fracture			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Scar			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Skeletal injury			
subjects affected / exposed	2 / 109 (1.83%)		
occurrences (all)	2		
Skin abrasion			
subjects affected / exposed	2 / 109 (1.83%)		
occurrences (all)	2		
Investigations			
Blood pressure increased			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	2		
Aspartate aminotransferase abnormal			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Alanine aminotransferase increased			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Intraocular pressure increased			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Transaminases increased			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
White blood cell count decreased			
subjects affected / exposed	2 / 109 (1.83%)		
occurrences (all)	3		
Weight increased			
subjects affected / exposed	1 / 109 (0.92%)		

occurrences (all)	1		

Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Epistaxis			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Catarrh			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Rhinitis allergic			
subjects affected / exposed	2 / 109 (1.83%)		
occurrences (all)	2		
Tonsillar hypertrophy			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Oropharyngeal pain			
subjects affected / exposed	2 / 109 (1.83%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 109 (1.83%)		
occurrences (all)	2		
Iron deficiency anaemia			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Lymphadenitis			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Neutropenia			
subjects affected / exposed	1 / 109 (0.92%)		

occurrences (all)	1		
Thrombocytopenia			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Leukopenia			
subjects affected / exposed	4 / 109 (3.67%)		
occurrences (all)	4		
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 109 (4.59%)		
occurrences (all)	5		
Dizziness			
subjects affected / exposed	3 / 109 (2.75%)		
occurrences (all)	3		
Sciatica			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Migraine			
subjects affected / exposed	2 / 109 (1.83%)		
occurrences (all)	2		
Syncope			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Narcolepsy			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Eye disorders			
Iridocyclitis			
subjects affected / exposed	5 / 109 (4.59%)		
occurrences (all)	5		
Maculopathy			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Scleral haemorrhage			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		

Uveitis			
subjects affected / exposed	4 / 109 (3.67%)		
occurrences (all)	4		
Ear and labyrinth disorders			
Tympanic membrane disorder			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Eustachian tube disorder			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Vertigo			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Tympanic membrane perforation			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 109 (1.83%)		
occurrences (all)	2		
Abdominal pain upper			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Anal fistula			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Aphthous ulcer			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Colitis			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Constipation			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	6 / 109 (5.50%)		

occurrences (all)	6		
Dyspepsia			
subjects affected / exposed	3 / 109 (2.75%)		
occurrences (all)	3		
Enteritis			
subjects affected / exposed	2 / 109 (1.83%)		
occurrences (all)	2		
Food poisoning			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Gastritis			
subjects affected / exposed	4 / 109 (3.67%)		
occurrences (all)	4		
Nausea			
subjects affected / exposed	5 / 109 (4.59%)		
occurrences (all)	5		
Pneumoperitoneum			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Toothache			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	4 / 109 (3.67%)		
occurrences (all)	4		
Enterocolitis			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Renal and urinary disorders			
Renal colic			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Haematuria			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Hepatobiliary disorders			

Hypertransaminasaemia subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all)	3 / 109 (2.75%) 3		
Acne conglobata subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		
Dermatitis atopic subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		
Acne cystic subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		
Hair colour changes subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		
Rash subjects affected / exposed occurrences (all)	3 / 109 (2.75%) 3		
Psoriasis subjects affected / exposed occurrences (all)	3 / 109 (2.75%) 3		
Rash erythematous subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		
Skin lesion subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		
Photosensitivity reaction subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		
Musculoskeletal and connective tissue disorders			

Arthralgia				
subjects affected / exposed	11 / 109 (10.09%)			
occurrences (all)	16			
Arthritis				
subjects affected / exposed	3 / 109 (2.75%)			
occurrences (all)	3			
Back pain				
subjects affected / exposed	7 / 109 (6.42%)			
occurrences (all)	7			
Bone pain				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Bone swelling				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Haematoma muscle				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Groin pain				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Intervertebral disc disorder				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Joint effusion				
subjects affected / exposed	3 / 109 (2.75%)			
occurrences (all)	5			
Intervertebral disc protrusion				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Juvenile idiopathic arthritis				
subjects affected / exposed	4 / 109 (3.67%)			
occurrences (all)	4			
Joint swelling				
subjects affected / exposed	2 / 109 (1.83%)			
occurrences (all)	2			

Joint laxity				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Muscle contracture				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Myalgia				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Pain in jaw				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Pain in extremity				
subjects affected / exposed	3 / 109 (2.75%)			
occurrences (all)	3			
Osteonecrosis				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Tendonitis				
subjects affected / exposed	3 / 109 (2.75%)			
occurrences (all)	3			
Spinal pain				
subjects affected / exposed	2 / 109 (1.83%)			
occurrences (all)	2			
Neck pain				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Tenosynovitis				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Plantar fasciitis				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Synovitis				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			

Infections and infestations			
Acarodermatitis			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Conjunctivitis			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Anal abscess			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Acute sinusitis			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Cystitis			
subjects affected / exposed	4 / 109 (3.67%)		
occurrences (all)	4		
Diarrhoea infectious			
subjects affected / exposed	2 / 109 (1.83%)		
occurrences (all)	2		
Bronchitis			
subjects affected / exposed	12 / 109 (11.01%)		
occurrences (all)	14		
Ear infection			
subjects affected / exposed	5 / 109 (4.59%)		
occurrences (all)	10		
Gastrointestinal viral infection			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Folliculitis			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Enterovirus infection			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Gingivitis			
subjects affected / exposed	1 / 109 (0.92%)		

occurrences (all)	1			
Infectious mononucleosis				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Influenza				
subjects affected / exposed	8 / 109 (7.34%)			
occurrences (all)	11			
Laryngitis				
subjects affected / exposed	3 / 109 (2.75%)			
occurrences (all)	3			
Nasopharyngitis				
subjects affected / exposed	8 / 109 (7.34%)			
occurrences (all)	9			
Oral herpes				
subjects affected / exposed	2 / 109 (1.83%)			
occurrences (all)	11			
Orchitis				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Otitis externa				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Otitis media				
subjects affected / exposed	3 / 109 (2.75%)			
occurrences (all)	3			
Otitis media acute				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Paronychia				
subjects affected / exposed	3 / 109 (2.75%)			
occurrences (all)	3			
Periodontitis				
subjects affected / exposed	3 / 109 (2.75%)			
occurrences (all)	3			
Pertussis				
subjects affected / exposed	1 / 109 (0.92%)			

occurrences (all)	1			
Pharyngitis				
subjects affected / exposed	21 / 109 (19.27%)			
occurrences (all)	54			
Pharyngotonsillitis				
subjects affected / exposed	4 / 109 (3.67%)			
occurrences (all)	4			
Pneumonia				
subjects affected / exposed	4 / 109 (3.67%)			
occurrences (all)	4			
Pulpitis dental				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Respiratory tract infection				
subjects affected / exposed	3 / 109 (2.75%)			
occurrences (all)	3			
Respiratory tract infection viral				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	3			
Sinusitis				
subjects affected / exposed	8 / 109 (7.34%)			
occurrences (all)	8			
Septic shock				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Suspected COVID-19				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Staphylococcal skin infection				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	6			
Tinea versicolour				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Tonsillitis				
subjects affected / exposed	9 / 109 (8.26%)			

occurrences (all)	17			
Vaginal infection				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Urinary tract infection				
subjects affected / exposed	2 / 109 (1.83%)			
occurrences (all)	2			
Upper respiratory tract infection				
subjects affected / exposed	28 / 109 (25.69%)			
occurrences (all)	85			
Varicella				
subjects affected / exposed	3 / 109 (2.75%)			
occurrences (all)	3			
Viraemia				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Viral infection				
subjects affected / exposed	4 / 109 (3.67%)			
occurrences (all)	4			
Wound infection				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Viral upper respiratory tract infection				
subjects affected / exposed	2 / 109 (1.83%)			
occurrences (all)	2			
Viral tonsillitis				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Gastroenteritis				
subjects affected / exposed	10 / 109 (9.17%)			
occurrences (all)	10			
Gastroenteritis viral				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Herpes simplex				
subjects affected / exposed	1 / 109 (0.92%)			

occurrences (all)	1		
Rhinitis			
subjects affected / exposed	4 / 109 (3.67%)		
occurrences (all)	5		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 July 2012	Changes in study title, schedule of activities and study objectives.
09 March 2015	Modification in adverse event reporting section and communication of results by Pfizer.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The data for endpoint analysis taken from statistical analysis plan based on the study team discretion.

Notes: