



Clinical trial results:

A 2-Part Open-label Study to Assess the Clinical Benefit and Long-term Safety of Etanercept in Children and Adolescents With Extended Oligoarticular Juvenile Idiopathic Arthritis, Enthesitis-Related Arthritis, or Psoriatic Arthritis

Summary

EudraCT number	2009-012520-84
Trial protocol	HU DE BE CZ FR SI ES SE SK LT NL LV GR DK IT Outside
Global end of trial date	50/EEA 30 January 2013

Results information

Result version number	v1 (current)
This version publication date	01 June 2016
First version publication date	18 July 2015

Trial information

Trial identification

Sponsor protocol code	B1801014
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00962741
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: 0881A1-3338

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-000299-PIP01-08
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 December 2013
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	30 January 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Part 1: To assess the clinical benefit of etanercept in subjects with extended oligoarticular juvenile idiopathic arthritis (JIA), enthesitis-related arthritis (ERA), or psoriatic arthritis (PsA).

Part 2: To assess the long-term safety of etanercept in subjects with extended oligoarticular JIA, ERA, or 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 Conference on 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	23 November 2009
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	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	Belgium: 10
Country: Number of subjects enrolled	Czech Republic: 5
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	Serbia: 14
Country: Number of subjects enrolled	Australia: 4
Country: Number of subjects enrolled	Russian Federation: 11
Country: Number of subjects enrolled	Colombia: 3

Country: Number of subjects enrolled	Mexico: 2
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: -

Pre-assignment

Screening details:

Total subjects enrolled were 127 in 19 countries from 23 November 2009 to 30 January 2013.

Period 1

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

Arms

Arm title	Etanercept
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Arm description:

Etanercept was administered 0.8 milligram per kilogram (mg/kg) up to a maximum dose of 50 mg once weekly subcutaneously for 96 weeks.

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 subcutaneously for 96 weeks.

Number of subjects in period 1	Etanercept
Started	127
Completed	119
Not completed	8
Consent withdrawn by subject	1
'Failed to return '	3
Lost to follow-up	2
'drug ineffective+prohibited drug taken '	1
Lack of efficacy	1

Baseline characteristics

Reporting groups

Reporting group title	Etanercept
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Reporting group description:

Etanercept was administered 0.8 milligram per kilogram (mg/kg) up to a maximum dose of 50 mg once weekly subcutaneously for 96 weeks.

Reporting group values	Etanercept	Total	
Number of subjects	127	127	
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	11.7 ± 4.51	-	
Gender categorical Units: Subjects			
Female	72	72	
Male	55	55	

End points

End points reporting groups

Reporting group title	Etanercept
Reporting group description:	
Etanercept was administered 0.8 milligram per kilogram (mg/kg) up to a maximum dose of 50 mg once weekly subcutaneously for 96 weeks.	

Primary: Percentage of Subjects With an American College of Rheumatology Pediatric 30 (ACR Pedi 30) Response at Week 12

End point title	Percentage of Subjects With an American College of Rheumatology Pediatric 30 (ACR Pedi 30) Response at Week 12 ^[1]
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End point description:

ACR Pedi 30 response: greater than or equal to (\geq)30 percent (%) improvement from baseline in 3 of 6 criteria with worsening greater than ($>$)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. Modified Intent-to-Treat (mITT) population included all subjects who received at least 1 dose of the study medication.

End point type	Primary
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End point timeframe:

Week 12

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	123 ^[2]			
Units: Percentage of subjects				
number (confidence interval 95%)	88.6 (81.6 to 93.6)			

Notes:

[2] - 'N'(Number of subjects analyzed) signified those subjects who were evaluable for measure at week 12.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects With an ACR Pedi 30 Response

End point title	Percentage of subjects With an ACR Pedi 30 Response
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End point description:

ACR Pedi 30 response: \geq 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) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein. mITT population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 126)	71.4 (62.7 to 79.1)			
Week 8 (N = 121)	88.4 (81.3 to 93.5)			
Week 12 (N = 123)	88.6 (81.6 to 93.6)			
Week 24 (N = 122)	94.3 (88.5 to 97.7)			
Week 36 (N = 120)	95.8 (90.5 to 98.6)			
Week 48 (N = 119)	94.1 (88.3 to 97.6)			
Week 60 (N = 116)	95.7 (90.2 to 98.6)			
Week 72 (N = 114)	96.5 (91.3 to 99)			
Week 84 (N = 113)	93.8 (87.7 to 97.5)			
Week 96 (N = 108)	99.1 (94.9 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 30 Response: Extended Oligoarticular Juvenile Idiopathic Arthritis (eoJIA) Sub-population

End point title	Percentage of Subjects With an ACR Pedi 30 Response: Extended Oligoarticular Juvenile Idiopathic Arthritis (eoJIA) Sub-population
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End point description:

ACR Pedi 30 response: $\geq 30\%$ 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) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein. eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease and had progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 59)	67.8 (54.4 to 79.4)			
Week 8 (N = 56)	87.5 (75.9 to 94.8)			
Week 12 (N = 58)	89.7 (78.8 to 96.1)			
Week 24 (N = 58)	94.8 (85.6 to 98.9)			
Week 36 (N = 57)	94.7 (85.4 to 98.9)			
Week 48 (N = 57)	96.5 (87.9 to 99.6)			
Week 60 (N = 56)	98.2 (90.4 to 100)			
Week 72 (N = 55)	98.2 (90.3 to 100)			
Week 84 (N = 55)	98.2 (90.3 to 100)			
Week 96 (N = 53)	100 (93.3 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 30 Response: Enthesitis-Related Arthritis (ERA) Sub-population

End point title	Percentage of Subjects With an ACR Pedi 30 Response: Enthesitis-Related Arthritis (ERA) Sub-population
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End point description:

ACR Pedi 30 response: $\geq 30\%$ 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) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks). ERA: subjects with arthritis (Ar) or (/) enthesitis, any 2: sacroiliac joint tenderness/inflammatory (Ifm) lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6 years; acute anterior uveitis (AAU)/AAU first-degree relative.

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 38)	84.2 (68.7 to 94)			
Week 8 (N = 36)	91.7 (77.5 to 98.2)			
Week 12 (N = 36)	83.3 (67.2 to 93.6)			
Week 24 (N = 36)	91.7 (77.5 to 98.2)			
Week 36 (N = 35)	97.1 (85.1 to 99.9)			
Week 48 (N = 34)	91.2 (76.3 to 98.1)			
Week 60 (N = 33)	90.9 (75.7 to 98.1)			
Week 72 (N = 32)	93.8 (79.2 to 99.2)			
Week 84 (N = 31)	90.3 (74.2 to 98)			
Week 96 (N = 30)	100 (88.4 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 30 Response: Psoriatic Arthritis (PsA) Sub-population

End point title	Percentage of Subjects With an ACR Pedi 30 Response: Psoriatic Arthritis (PsA) Sub-population
End point description:	
ACR Pedi 30 response: $\geq 30\%$ 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) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Secondary
End point timeframe:	
Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 29)	62.1 (42.3 to 79.3)			
Week 8 (N = 29)	86.2 (68.3 to 96.1)			
Week 12 (N = 29)	93.1 (77.2 to 99.2)			
Week 24 (N = 28)	96.4 (81.7 to 99.9)			
Week 36 (N = 28)	96.4 (81.7 to 99.9)			
Week 48 (N = 28)	92.9 (76.5 to 99.1)			
Week 60 (N = 27)	96.3 (81 to 99.9)			
Week 72 (N = 27)	96.3 (81 to 99.9)			
Week 84 (N = 27)	88.9 (70.8 to 97.6)			
Week 96 (N = 25)	96 (79.6 to 99.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 50 Response

End point title	Percentage of Subjects With an ACR Pedi 50 Response
End point description:	
ACR Pedi 50 response: $\geq 50\%$ 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 disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. mITT population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Secondary
End point timeframe:	
Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 125)	51.2 (42.1 to 60.2)			

Week 8 (N = 121)	76.9 (68.3 to 84)			
Week 12 (N = 122)	81.1 (73.1 to 87.7)			
Week 24 (N = 122)	88.5 (81.5 to 93.6)			
Week 36 (N = 120)	88.3 (81.2 to 93.5)			
Week 48 (N = 119)	93.3 (87.2 to 97.1)			
Week 60 (N = 116)	92.2 (85.8 to 96.4)			
Week 72 (N = 114)	93.9 (87.8 to 97.5)			
Week 84 (N = 113)	91.2 (84.3 to 95.7)			
Week 96 (N = 108)	98.1 (93.5 to 99.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 50 Response: eoJIA Sub-population

End point title	Percentage of Subjects With an ACR Pedi 50 Response: eoJIA Sub-population
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End point description:

ACR Pedi 50 response: $\geq 50\%$ 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 disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease and had progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 58)	51.7 (38.2 to 65)			
Week 8 (N = 56)	75 (61.6 to 85.6)			
Week 12 (N = 58)	79.3 (66.6 to 88.8)			
Week 24 (N = 58)	86.2 (74.6 to 93.9)			

Week 36 (N = 57)	91.2 (80.7 to 97.1)			
Week 48 (N = 57)	94.7 (85.4 to 98.9)			
Week 60 (N = 56)	92.9 (82.7 to 98)			
Week 72 (N = 55)	96.4 (87.5 to 99.6)			
Week 84 (N = 55)	96.4 (87.5 to 99.6)			
Week 96 (N = 53)	100 (93.3 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 50 Response: ERA Sub-population

End point title	Percentage of Subjects With an ACR Pedi 50 Response: ERA Sub-population
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End point description:

ACR Pedi 50 response: $\geq 50\%$ 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 disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male > 6 years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 38)	63.2 (46 to 78.2)			
Week 8 (N = 36)	86.1 (70.5 to 95.3)			
Week 12 (N = 35)	80 (63.1 to 91.6)			
Week 24 (N = 36)	86.1 (70.5 to 95.3)			
Week 36 (N = 35)	82.9 (66.4 to 93.4)			
Week 48 (N = 34)	91.2 (76.3 to 98.1)			

Week 60 (N = 33)	87.9 (71.8 to 96.6)			
Week 72 (N = 32)	90.6 (75 to 98)			
Week 84 (N = 31)	83.9 (66.3 to 94.5)			
Week 96 (N = 30)	96.7 (82.8 to 99.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 50 Response: PsA Sub-population

End point title	Percentage of Subjects With an ACR Pedi 50 Response: PsA Sub-population
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End point description:

ACR Pedi 50 response: $\geq 50\%$ 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 disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 29)	34.5 (17.9 to 54.3)			
Week 8 (N = 29)	69 (49.2 to 84.7)			
Week 12 (N = 29)	86.2 (68.3 to 96.1)			
Week 24 (N = 28)	96.4 (81.7 to 99.9)			
Week 36 (N = 28)	89.3 (71.8 to 97.7)			
Week 48 (N = 28)	92.9 (76.5 to 99.1)			
Week 60 (N = 27)	96.3 (81 to 99.9)			
Week 72 (N = 27)	92.6 (75.7 to 99.1)			
Week 84 (N = 27)	88.9 (70.8 to 97.6)			
Week 96 (N = 25)	96 (79.6 to 99.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 70 Response

End point title	Percentage of Subjects With an ACR Pedi 70 Response
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End point description:

ACR Pedi 70 response: $\geq 70\%$ 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 disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. mITT population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 126)	26.2 (18.8 to 34.8)			
Week 8 (N = 121)	47.1 (38 to 56.4)			
Week 12 (N = 122)	61.5 (52.2 to 70.1)			
Week 24 (N = 122)	71.3 (62.4 to 79.1)			
Week 36 (N = 120)	73.3 (64.5 to 81)			
Week 48 (N = 119)	79.8 (71.5 to 86.6)			
Week 60 (N = 115)	81.7 (73.5 to 88.3)			
Week 72 (N = 114)	84.2 (76.2 to 90.4)			
Week 84 (N = 113)	87.6 (80.1 to 93.1)			
Week 96 (N = 108)	92.6 (85.9 to 96.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 70 Response: eoJIA Sub-population

End point title	Percentage of Subjects With an ACR Pedi 70 Response: eoJIA Sub-population
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End point description:

ACR Pedi 70 response: $\geq 70\%$ 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 disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease and had progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 59)	28.8 (17.8 to 42.1)			
Week 8 (N = 56)	51.8 (38 to 65.3)			
Week 12 (N = 58)	63.8 (50.1 to 76)			
Week 24 (N = 58)	70.7 (57.3 to 81.9)			
Week 36 (N = 57)	75.4 (62.2 to 85.9)			
Week 48 (N = 57)	77.2 (64.2 to 87.3)			
Week 60 (N = 55)	80 (67 to 89.6)			
Week 72 (N = 55)	85.5 (73.3 to 93.5)			
Week 84 (N = 55)	90.9 (80 to 97)			
Week 96 (N = 53)	94.3 (84.3 to 98.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 70 Response: ERA Sub-population

End point title	Percentage of Subjects With an ACR Pedi 70 Response: ERA Sub-population
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End point description:

ACR Pedi 70 response: $\geq 70\%$ 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 disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male > 6 years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 38)	28.9 (15.4 to 45.9)			
Week 8 (N = 36)	52.8 (35.5 to 69.6)			
Week 12 (N = 35)	71.4 (53.7 to 85.4)			
Week 24 (N = 36)	80.6 (64 to 91.8)			
Week 36 (N = 35)	77.1 (59.9 to 89.6)			
Week 48 (N = 34)	85.3 (68.9 to 95)			
Week 60 (N = 33)	81.8 (64.5 to 93)			
Week 72 (N = 32)	81.3 (63.6 to 92.8)			
Week 84 (N = 31)	80.6 (62.5 to 92.5)			
Week 96 (N = 30)	86.7 (69.3 to 96.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 70 Response: PsA Sub-population

End point title	Percentage of Subjects With an ACR Pedi 70 Response: PsA Sub-population
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End point description:

ACR Pedi 70 response: $\geq 70\%$ 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 disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
End point timeframe:	
Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 29)	17.2 (5.8 to 35.8)			
Week 8 (N = 29)	31 (15.3 to 50.8)			
Week 12 (N = 29)	44.8 (26.4 to 64.3)			
Week 24 (N = 28)	60.7 (40.6 to 78.5)			
Week 36 (N = 28)	64.3 (44.1 to 81.4)			
Week 48 (N = 28)	78.6 (59 to 91.7)			
Week 60 (N = 27)	85.2 (66.3 to 95.8)			
Week 72 (N = 27)	85.2 (66.3 to 95.8)			
Week 84 (N = 27)	88.9 (70.8 to 97.6)			
Week 96 (N = 25)	96 (79.6 to 99.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 90 Response

End point title	Percentage of Subjects With an ACR Pedi 90 Response
End point description:	
ACR Pedi 90 response: \geq 90% 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 disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. mITT population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Secondary
End point timeframe:	
Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 126)	6.3 (2.8 to 12.1)			
Week 8 (N = 121)	14.9 (9.1 to 22.5)			
Week 12 (N = 121)	29.8 (21.8 to 38.7)			
Week 24 (N = 122)	43.4 (34.5 to 52.7)			
Week 36 (N = 120)	47.5 (38.3 to 56.8)			
Week 48 (N = 119)	50.4 (41.1 to 59.7)			
Week 60 (N = 115)	53 (43.5 to 62.4)			
Week 72 (N = 113)	60.2 (50.5 to 69.3)			
Week 84 (N = 113)	64.6 (55 to 73.4)			
Week 96 (N = 107)	65.4 (55.6 to 74.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 90 Response:eoJIA Sub-population

End point title	Percentage of Subjects With an ACR Pedi 90 Response:eoJIA Sub-population
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End point description:

ACR Pedi 90 response: $\geq 90\%$ 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 disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease and had progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 59)	6.8 (1.9 to 16.5)			
Week 8 (N = 56)	16.1 (7.6 to 28.3)			
Week 12 (N = 58)	27.6 (16.7 to 40.9)			
Week 24 (N = 58)	53.4 (39.9 to 66.7)			
Week 36 (N = 57)	49.1 (35.6 to 62.7)			
Week 48 (N = 57)	52.6 (39 to 66)			
Week 60 (N = 55)	52.7 (38.8 to 66.3)			
Week 72 (N = 54)	61.1 (46.9 to 74.1)			
Week 84 (N = 55)	67.3 (53.3 to 79.3)			
Week 96 (N = 53)	62.3 (47.9 to 75.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 90 Response: ERA Sub-population

End point title	Percentage of Subjects With an ACR Pedi 90 Response: ERA Sub-population
End point description:	
ACR Pedi 90 response: $\geq 90\%$ 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 disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male > 6 years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Secondary
End point timeframe:	
Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 38)	10.5 (2.9 to 24.8)			
Week 8 (N = 36)	22.2 (10.1 to 39.2)			
Week 12 (N = 35)	45.7 (28.8 to 63.4)			
Week 24 (N = 36)	41.7 (25.5 to 59.2)			
Week 36 (N = 35)	48.6 (31.4 to 66)			
Week 48 (N = 34)	50 (32.4 to 67.6)			
Week 60 (N = 33)	57.6 (39.2 to 74.5)			
Week 72 (N = 32)	71.9 (53.3 to 86.3)			
Week 84 (N = 31)	64.5 (45.4 to 80.8)			
Week 96 (N = 30)	66.7 (47.2 to 82.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 90 Response: PsA Sub-population

End point title	Percentage of Subjects With an ACR Pedi 90 Response: PsA Sub-population
End point description:	
ACR Pedi 90 response: $\geq 90\%$ 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 disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Secondary
End point timeframe:	
Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 29)	0 (0 to 11.9)			
Week 8 (N = 29)	3.4 (0.1 to 17.8)			
Week 12 (N = 28)	14.3 (4 to 32.7)			
Week 24 (N = 28)	25 (10.7 to 44.9)			
Week 36 (N = 28)	42.9 (24.5 to 62.8)			
Week 48 (N = 28)	46.4 (27.5 to 66.1)			
Week 60 (N = 27)	48.1 (28.7 to 68.1)			
Week 72 (N = 27)	44.4 (25.5 to 64.7)			
Week 84 (N = 27)	59.3 (38.8 to 77.6)			
Week 96 (N = 24)	70.8 (48.3 to 87.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 100 Response

End point title	Percentage of Subjects With an ACR Pedi 100 Response
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: 1) physician's global assessment of disease activity, 2) parent/patient global assessment of disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. mITT population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Secondary
End point timeframe:	
Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 126)	3.2 (0.9 to 7.9)			
Week 8 (N = 121)	6.6 (2.9 to 12.6)			

Week 12 (N = 122)	23 (15.8 to 31.4)			
Week 24 (N = 122)	33.6 (25.3 to 42.7)			
Week 36 (N = 120)	36.7 (28.1 to 45.9)			
Week 48 (N = 119)	40.3 (31.4 to 49.7)			
Week 60 (N = 114)	42.1 (32.9 to 51.7)			
Week 72 (N = 113)	49.6 (40 to 59.1)			
Week 84 (N = 112)	55.4 (45.7 to 64.8)			
Week 96 (N = 107)	54.2 (44.3 to 63.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 100 Response: eoJIA Sub-population

End point title	Percentage of Subjects With an ACR Pedi 100 Response: eoJIA Sub-population
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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: 1) physician's global assessment of disease activity, 2) parent/patient global assessment of disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease and had progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 59)	6.8 (1.9 to 16.5)			
Week 8 (N = 56)	8.9 (3 to 19.6)			
Week 12 (N = 58)	20.7 (11.2 to 33.4)			
Week 24 (N = 58)	39.7 (27 to 53.4)			
Week 36 (N = 57)	42.1 (29.1 to 55.9)			
Week 48 (N = 57)	47.4 (34 to 61)			

Week 60 (N = 55)	47.3 (33.7 to 61.2)			
Week 72 (N = 54)	51.9 (37.8 to 65.7)			
Week 84 (N = 55)	60 (45.9 to 73)			
Week 96 (N = 53)	54.7 (40.4 to 68.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 100 Response: ERA Sub-population

End point title	Percentage of Subjects With an ACR Pedi 100 Response: ERA Sub-population
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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: 1) physician's global assessment of disease activity, 2) parent/patient global assessment of disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA,sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male>6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 38)	0 (0 to 9.3)			
Week 8 (N = 36)	5.6 (0.7 to 18.7)			
Week 12 (N = 35)	34.3 (19.1 to 52.2)			
Week 24 (N = 36)	36.1 (20.8 to 53.8)			
Week 36 (N = 35)	34.3 (19.1 to 52.2)			
Week 48 (N = 34)	32.4 (17.4 to 50.5)			
Week 60 (N = 33)	42.4 (25.5 to 60.8)			
Week 72 (N = 32)	59.4 (40.6 to 76.3)			
Week 84 (N = 31)	54.8 (36 to 72.7)			
Week 96 (N = 30)	50 (31.3 to 68.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an ACR Pedi 100 Response: PsA Sub-population

End point title	Percentage of Subjects With an ACR Pedi 100 Response: PsA Sub-population
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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: 1) physician's global assessment of disease activity, 2) parent/patient global assessment of disease activity, 3) CHAQ 4) number of active joints 5) number of joints with limited range of motion and 6) C-reactive protein at each visit. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (N = 29)	0 (0 to 11.9)			
Week 8 (N = 29)	3.4 (0.1 to 17.8)			
Week 12 (N = 29)	13.8 (3.9 to 31.7)			
Week 24 (N = 28)	17.9 (6.1 to 36.9)			
Week 36 (N = 28)	28.6 (13.2 to 48.7)			
Week 48 (N = 28)	35.7 (18.6 to 55.9)			
Week 60 (N = 26)	30.8 (14.3 to 51.8)			
Week 72 (N = 27)	33.3 (16.5 to 54)			
Week 84 (N = 26)	46.2 (36.6 to 66.6)			
Week 96 (N = 24)	58.3 (36.6 to 77.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Physician's Global Assessment (PGA) of Disease Activity

End point title	Physician's Global Assessment (PGA) of Disease Activity
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End point description:

PGA of Disease Activity was measured on a 21-circle Visual Analog Scale (VAS) ranging from 0 to 10, with 0 = no disease activity and 10= Maximum disease activity. mITT population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 127)	5.02 (± 1.75)			
Week 4 (N = 126)	2.78 (± 1.78)			
Week 8 (N = 121)	2 (± 1.55)			
Week 12 (N = 123)	1.5 (± 1.3)			
Week 24 (N = 122)	1.15 (± 1.22)			
Week 36 (N = 120)	1.05 (± 1.17)			
Week 48 (N = 119)	1.03 (± 1.19)			
Week 60 (N = 116)	0.88 (± 0.99)			
Week 72 (N = 113)	0.78 (± 0.97)			
Week 84 (N = 113)	0.78 (± 1.04)			
Week 96 (N = 108)	0.62 (± 0.79)			

Statistical analyses

No statistical analyses for this end point

Secondary: Physician's Global Assessment (PGA) of Disease Activity: eoJIA Sub-population

End point title	Physician's Global Assessment (PGA) of Disease Activity: eoJIA Sub-population
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End point description:

PGA of Disease Activity was measured on a 21-circle Visual Analog Scale (VAS) ranging from 0 to 10, with 0 = no disease activity and 10= Maximum disease activity. eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease that progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 60)	4.96 (± 1.76)			
Week 4 (N = 59)	2.73 (± 1.8)			
Week 8 (N = 56)	1.8 (± 1.62)			
Week 12 (N = 58)	1.4 (± 1.3)			
Week 24 (N = 58)	1.03 (± 1.34)			
Week 36 (N = 57)	0.89 (± 1.25)			
Week 48 (N = 57)	0.88 (± 1.2)			
Week 60 (N = 56)	0.83 (± 1.06)			
Week 72 (N = 54)	0.72 (± 0.99)			
Week 84 (N = 55)	0.6 (± 0.86)			
Week 96 (N = 53)	0.59 (± 0.81)			

Statistical analyses

No statistical analyses for this end point

Secondary: Physician's Global Assessment (PGA) of Disease Activity: ERA Sub-population

End point title	Physician's Global Assessment (PGA) of Disease Activity: ERA Sub-population
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End point description:

PGA of Disease Activity was measured on a 21-circle Visual Analog Scale (VAS) ranging from 0 to 10, with 0 = no disease activity and 10= Maximum disease activity. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6 years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 38)	5.39 (± 1.94)			
Week 4 (N = 38)	2.71 (± 1.94)			
Week 8 (N = 36)	2.19 (± 1.5)			
Week 12 (N = 36)	1.53 (± 1.34)			
Week 24 (N = 36)	1.32 (± 1.12)			
Week 36 (N = 35)	1.21 (± 1.1)			
Week 48 (N = 34)	1.16 (± 1.14)			
Week 60 (N = 33)	0.8 (± 0.87)			
Week 72 (N = 32)	0.78 (± 0.98)			
Week 84 (N = 31)	0.84 (± 1.09)			
Week 96 (N = 30)	0.62 (± 0.67)			

Statistical analyses

No statistical analyses for this end point

Secondary: Physician's Global Assessment (PGA) of Disease Activity: PsA Sub-population

End point title	Physician's Global Assessment (PGA) of Disease Activity: PsA Sub-population
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End point description:

PGA of Disease Activity was measured on a 21-circle Visual Analog Scale (VAS) ranging from 0 to 10, with 0 = no disease activity and 10= Maximum disease activity. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 29)	4.66 (± 1.42)			
Week 4 (N = 29)	2.98 (± 1.56)			
Week 8 (N = 29)	2.14 (± 1.49)			
Week 12 (N = 29)	1.69 (± 1.28)			
Week 24 (N = 28)	1.18 (± 1.06)			
Week 36 (N = 28)	1.2 (± 1.09)			
Week 48 (N = 28)	1.18 (± 1.22)			

Week 60 (N = 27)	1.06 (± 0.99)			
Week 72 (N = 27)	0.89 (± 0.93)			
Week 84 (N = 27)	1.07 (± 1.25)			
Week 96 (N = 25)	0.66 (± 0.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Subject/Parent Global Assessment

End point title	Subject/Parent Global Assessment
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End point description:

Subject/Parent Global Assessment was assessed by the subject's parent using a 21-circle VAS ranging from 0 to 10, with 0 = very well and 10 = very poor. mITT population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 127)	4.96 (± 2.33)			
Week 4 (N = 126)	3.22 (± 2.23)			
Week 8 (N = 121)	2.79 (± 2.1)			
Week 12 (N = 123)	2.21 (± 1.84)			
Week 24 (N = 122)	1.79 (± 1.75)			
Week 36 (N = 120)	1.74 (± 1.97)			
Week 48 (N = 119)	1.65 (± 1.88)			
Week 60 (N = 116)	1.33 (± 1.56)			
Week 72 (N = 114)	1.29 (± 1.63)			
Week 84 (N = 113)	1.17 (± 1.56)			
Week 96 (N = 109)	0.97 (± 1.31)			

Statistical analyses

No statistical analyses for this end point

Secondary: Subject/Parent Global Assessment: eoJIA Sub-population

End point title	Subject/Parent Global Assessment: eoJIA Sub-population
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End point description:

Subject/Parent Global Assessment was assessed by the subject's parent using a 21-circle VAS ranging from 0 to 10, with 0 = very well and 10 = very poor. eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease that progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 60)	4.82 (± 2.44)			
Week 4 (N = 59)	2.82 (± 2.11)			
Week 8 (N = 56)	2.38 (± 2.02)			
Week 12 (N = 58)	1.97 (± 1.81)			
Week 24 (N = 58)	1.51 (± 1.69)			
Week 36 (N = 57)	1.56 (± 2.07)			
Week 48 (N = 57)	1.32 (± 1.82)			
Week 60 (N = 56)	1.29 (± 1.54)			
Week 72 (N = 55)	1.17 (± 1.55)			
Week 84 (N = 55)	0.9 (± 1.21)			
Week 96 (N = 54)	1 (± 1.43)			

Statistical analyses

No statistical analyses for this end point

Secondary: Subject/Parent Global Assessment: ERA Sub-population

End point title	Subject/Parent Global Assessment: ERA Sub-population
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End point description:

Subject/Parent Global Assessment was assessed by the subject's parent using a 21-circle VAS ranging from 0 to 10, with 0 = very well and 10 = very poor. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male>6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 38)	5.43 (± 2.26)			
Week 4 (N = 38)	3.62 (± 2.43)			
Week 8 (N = 36)	3.19 (± 2.26)			
Week 12 (N = 36)	2.56 (± 2.13)			
Week 24 (N = 36)	2.26 (± 2.03)			
Week 36 (N = 35)	2.04 (± 2.05)			
Week 48 (N = 34)	2.07 (± 2.14)			
Week 60 (N = 33)	1.39 (± 1.74)			
Week 72 (N = 32)	1.39 (± 1.8)			
Week 84 (N = 31)	1.29 (± 1.6)			
Week 96 (N = 30)	0.93 (± 1.19)			

Statistical analyses

No statistical analyses for this end point

Secondary: Subject/Parent Global Assessment: PsA Sub-population

End point title	Subject/Parent Global Assessment: PsA Sub-population
End point description:	
Subject/Parent Global Assessment was assessed by the subject's parent using a 21-circle VAS ranging from 0 to 10, with 0 = very well and 10 = very poor. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Secondary
End point timeframe:	
Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 29)	4.62 (± 2.17)			
Week 4 (N = 29)	3.5 (± 2.14)			
Week 8 (N = 29)	3.1 (± 1.97)			
Week 12 (N = 29)	2.26 (± 1.46)			
Week 24 (N = 28)	1.75 (± 1.38)			
Week 36 (N = 28)	1.73 (± 1.64)			
Week 48 (N = 28)	1.82 (± 1.61)			
Week 60 (N = 27)	1.33 (± 1.42)			
Week 72 (N = 27)	1.39 (± 1.64)			

Week 84 (N = 27)	1.59 (± 2.05)			
Week 96 (N = 25)	0.96 (± 1.22)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Active Joints

End point title	Number of Active Joints
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End point description:

Active joints: Joints that were swollen or, in absence of swelling, joints with limited motion with pain and/or tenderness. Joints were coded as: 0= no swelling, limitation of motion, or pain and/or tenderness on motion; 1= any swelling, limitation of motion, or pain and/or tenderness on motion; JR= joint replacement; NE= not evaluable. Total number of active joints= 73*(total number of active joints with counts > 0)/number of non-missing active joints. JR and NE were treated as missing. If > 36 active joint counts were missing, total number of active joints was defined as missing. mITT population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Joints				
arithmetic mean (standard deviation)				
Baseline (N = 127)	6.74 (± 4.59)			
Week 4 (N = 126)	3.17 (± 3.32)			
Week 8 (N = 121)	2.07 (± 2.67)			
Week 12 (N = 123)	1.72 (± 2.52)			
Week 24 (N = 122)	1.16 (± 2.06)			
Week 36 (N = 120)	0.99 (± 1.86)			
Week 48 (N = 119)	0.88 (± 1.92)			
Week 60 (N = 116)	0.87 (± 1.94)			
Week 72 (N = 114)	0.77 (± 1.97)			
Week 84 (N = 113)	0.81 (± 2.2)			
Week 96 (N = 109)	0.61 (± 2.06)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Active Joints: eoJIA Sub-population

End point title	Number of Active Joints: eoJIA Sub-population
End point description:	
Active joints: Joints that were swollen or, in absence of swelling, joints with limited motion with pain and/or tenderness. Joints were coded as: 0= no swelling, limitation of motion, or pain and/or tenderness on motion; 1= any swelling, limitation of motion, or pain and/or tenderness on motion; JR= joint replacement; NE= not evaluable. Total number of active joints= 73*(total number of active joints with counts > 0)/number of non-missing active joints. JR and NE were treated as missing. If > 36 active joint counts were missing, total number of active joints was defined as missing. eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease that progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Secondary
End point timeframe:	
Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Joints				
arithmetic mean (standard deviation)				
Baseline (N = 60)	7.58 (± 5.09)			
Week 4 (N = 59)	3.95 (± 3.75)			
Week 8 (N = 56)	2.46 (± 2.7)			
Week 12 (N = 58)	2.07 (± 2.77)			
Week 24 (N = 58)	1.34 (± 2.29)			
Week 36 (N = 57)	1.14 (± 1.97)			
Week 48 (N = 57)	1 (± 1.6)			
Week 60 (N = 56)	0.98 (± 1.63)			
Week 72 (N = 55)	0.73 (± 1.21)			
Week 84 (N = 55)	0.65 (± 1.16)			
Week 96 (N = 54)	0.5 (± 0.89)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Active Joints: ERA Sub-population

End point title	Number of Active Joints: ERA Sub-population
End point description:	
Active joints: Joints that were swollen or, in absence of swelling, joints with limited motion with pain and/or tenderness. Joints were coded as: 0= no swelling, limitation of motion, or pain and/or tenderness on motion; 1= any swelling, limitation of motion, or pain and/or tenderness on motion; JR= joint replacement; NE= not evaluable. Total number of active joints= 73*(total number of active joints with counts > 0)/number of non-missing active joints. JR and NE were treated as missing. If > 36 active joint counts were missing, total number of active joints was defined as missing. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Secondary

End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Joints				
arithmetic mean (standard deviation)				
Baseline (N = 38)	5.21 (± 3.57)			
Week 4 (N = 38)	2.4 (± 2.62)			
Week 8 (N = 36)	1.47 (± 2.25)			
Week 12 (N = 36)	1.08 (± 1.57)			
Week 24 (N = 36)	0.78 (± 1.07)			
Week 36 (N = 35)	0.74 (± 1.29)			
Week 48 (N = 34)	0.68 (± 1.09)			
Week 60 (N = 33)	0.48 (± 0.94)			
Week 72 (N = 32)	0.59 (± 1.21)			
Week 84 (N = 31)	0.68 (± 1.19)			
Week 96 (N = 30)	0.5 (± 0.94)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Active Joints: PsA Sub-population

End point title	Number of Active Joints: PsA Sub-population
End point description:	
Active joints: Joints that were swollen or, in absence of swelling, joints with limited motion with pain and/or tenderness. Joints were coded as: 0= no swelling, limitation of motion, or pain and/or tenderness on motion; 1= any swelling, limitation of motion, or pain and/or tenderness on motion; JR= joint replacement; NE= not evaluable. Total number of active joints= 73*(total number of active joints with counts > 0)/number of non-missing active joints. JR and NE were treated as missing. If > 36 active joint counts were missing, total number of active joints was defined as missing. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Secondary
End point timeframe:	
Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Joints				
arithmetic mean (standard deviation)				
Baseline (N = 29)	7 (± 4.33)			
Week 4 (N = 29)	2.59 (± 2.92)			
Week 8 (N = 29)	2.07 (± 3.05)			
Week 12 (N = 29)	1.79 (± 2.86)			
Week 24 (N = 28)	1.25 (± 2.47)			
Week 36 (N = 28)	1 (± 2.21)			
Week 48 (N = 28)	0.89 (± 3.03)			
Week 60 (N = 27)	1.11 (± 3.11)			
Week 72 (N = 27)	1.08 (± 3.45)			
Week 84 (N = 27)	1.3 (± 4.02)			
Week 96 (N = 25)	0.96 (± 4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Joints With Limitation of Motion

End point title	Number of Joints With Limitation of Motion
End point description:	
<p>The joints were assessed and coded as: 0= no limitation of motion; 1= any limitation of motion; JR= joint replacement; NE= not evaluable. Total number of joints with limitation of motion: 69*(total number of joints with counts of limitation of motion > 0)/number of non-missing limitation of motions. JR and NE were treated as missing. If > 34 counts of limitation of motion were missing, total number of joints with limitation of motion was defined as missing. mITT population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).</p>	
End point type	Secondary
End point timeframe:	
Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Joints				
arithmetic mean (standard deviation)				
Baseline (N = 127)	5.72 (± 4.22)			
Week 4 (N = 126)	3.2 (± 3.27)			
Week 8 (N = 121)	2.26 (± 3.41)			
Week 12 (N = 123)	1.62 (± 2.31)			
Week 24 (N = 122)	1.43 (± 2.03)			
Week 36 (N = 120)	1.39 (± 2.13)			
Week 48 (N = 119)	1.26 (± 2.51)			

Week 60 (N = 116)	1.41 (± 2.98)			
Week 72 (N = 114)	1.13 (± 2.36)			
Week 84 (N = 113)	1.41 (± 3.05)			
Week 96 (N = 109)	1.06 (± 2.71)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Joints With Limitation of Motion: eoJIA Sub-population

End point title	Number of Joints With Limitation of Motion: eoJIA Sub-population
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End point description:

The joints were assessed and coded as: 0= no limitation of motion; 1= any limitation of motion; JR= joint replacement; NE= not evaluable. Total number of joints with limitation of motion: 69*(total number of joints with counts of limitation of motion > 0)/number of non-missing limitation of motions. JR and NE were treated as missing. If > 34 counts of limitation of motion were missing, total number of joints with limitation of motion was defined as missing. eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease that progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Joints				
arithmetic mean (standard deviation)				
Baseline (N = 60)	6.33 (± 4.37)			
Week 4 (N = 59)	3.12 (± 2.74)			
Week 8 (N = 56)	2.23 (± 3.47)			
Week 12 (N = 58)	1.78 (± 2.25)			
Week 24 (N = 58)	1.4 (± 1.77)			
Week 36 (N = 57)	1.16 (± 1.54)			
Week 48 (N = 57)	1.05 (± 1.63)			
Week 60 (N = 56)	1.36 (± 2.56)			
Week 72 (N = 55)	0.89 (± 1.58)			
Week 84 (N = 55)	0.98 (± 2.08)			
Week 96 (N = 54)	0.74 (± 1.22)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Joints With Limitation of Motion: ERA Sub-population

End point title	Number of Joints With Limitation of Motion: ERA Sub-population
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End point description:

The joints were assessed and coded as: 0= no limitation of motion; 1= any limitation of motion; JR= joint replacement; NE= not evaluable. Total number of joints with limitation of motion: 69*(total number of joints with counts of limitation of motion > 0)/number of non-missing limitation of motions. JR and NE were treated as missing. If > 34 counts of limitation of motion were missing, total number of joints with limitation of motion was defined as missing. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male>6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Joints				
arithmetic mean (standard deviation)				
Baseline (N = 38)	4.84 (± 4)			
Week 4 (N = 38)	2.98 (± 3.73)			
Week 8 (N = 36)	2.28 (± 3.59)			
Week 12 (N = 36)	1.58 (± 2.94)			
Week 24 (N = 36)	1.53 (± 2.8)			
Week 36 (N = 35)	1.55 (± 2.69)			
Week 48 (N = 34)	1.53 (± 2.88)			
Week 60 (N = 33)	1.36 (± 3.26)			
Week 72 (N = 32)	1.19 (± 2.09)			
Week 84 (N = 31)	1.68 (± 3.17)			
Week 96 (N = 30)	1.33 (± 2.89)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Joints With Limitation of Motion: PsA Sub-population

End point title	Number of Joints With Limitation of Motion: PsA Sub-population
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End point description:

The joints were assessed and coded as: 0= no limitation of motion; 1= any limitation of motion; JR= joint replacement; NE= not evaluable. Total number of joints with limitation of motion: 69*(total number of joints with counts of limitation of motion > 0)/number of non-missing limitation of motions. JR and NE were treated as missing. If > 34 counts of limitation of motion were missing, total number of joints with limitation of motion was defined as missing. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Joints				
arithmetic mean (standard deviation)				
Baseline (N = 29)	5.62 (± 4.1)			
Week 4 (N = 29)	3.66 (± 3.66)			
Week 8 (N = 29)	2.28 (± 3.15)			
Week 12 (N = 29)	1.34 (± 1.4)			
Week 24 (N = 28)	1.36 (± 1.31)			
Week 36 (N = 28)	1.64 (± 2.39)			
Week 48 (N = 28)	1.36 (± 3.42)			
Week 60 (N = 27)	1.56 (± 3.51)			
Week 72 (N = 27)	1.56 (± 3.68)			
Week 84 (N = 27)	1.96 (± 4.34)			
Week 96 (N = 25)	1.4 (± 4.39)			

Statistical analyses

No statistical analyses for this end point

Secondary: C-reactive Protein (CRP)

End point title	C-reactive Protein (CRP)
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. mITT population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Secondary
End point timeframe: Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: mg/Liter (mg/L)				
arithmetic mean (standard deviation)				
Baseline (N = 127)	8.26 (± 14.7)			
Week 4 (N = 125)	3.29 (± 7.85)			

Week 8 (N = 121)	2.32 (± 3.92)			
Week 12 (N = 120)	2.47 (± 7.19)			
Week 24 (N = 120)	3.54 (± 10.72)			
Week 36 (N = 119)	2.81 (± 5.75)			
Week 48 (N = 117)	2.04 (± 3.94)			
Week 60 (N = 110)	2.16 (± 4.87)			
Week 72 (N = 111)	2.26 (± 4.01)			
Week 84 (N = 109)	3.98 (± 12.51)			
Week 96 (N = 103)	2.76 (± 5.27)			

Statistical analyses

No statistical analyses for this end point

Secondary: C-reactive Protein (CRP): eoJIA Sub-population

End point title	C-reactive Protein (CRP): eoJIA Sub-population
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. eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease that progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Secondary
End point timeframe: Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: mg/L				
arithmetic mean (standard deviation)				
Baseline (N = 60)	6.27 (± 10.59)			
Week 4 (N = 58)	3.45 (± 7.79)			
Week 8 (N = 56)	2.66 (± 5.05)			
Week 12 (N = 58)	3.36 (± 10.07)			
Week 24 (N = 56)	5.26 (± 15.34)			
Week 36 (N = 57)	3.25 (± 6.56)			
Week 48 (N = 55)	1.93 (± 4.2)			
Week 60 (N = 55)	2.76 (± 6.52)			
Week 72 (N = 55)	2.42 (± 4.28)			
Week 84 (N = 54)	3.94 (± 9.13)			
Week 96 (N = 52)	3.34 (± 6.62)			

Statistical analyses

No statistical analyses for this end point

Secondary: C-reactive Protein (CRP): ERA Sub-population

End point title	C-reactive Protein (CRP): ERA Sub-population
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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. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: mg/L				
arithmetic mean (standard deviation)				
Baseline (N = 38)	15.27 (± 21.52)			
Week 4 (N = 38)	4.37 (± 10.36)			
Week 8 (N = 36)	2.53 (± 3.3)			
Week 12 (N = 34)	1.87 (± 2.84)			
Week 24 (N = 36)	1.96 (± 2.04)			
Week 36 (N = 35)	3.24 (± 6.41)			
Week 48 (N = 34)	2.79 (± 4.89)			
Week 60 (N = 30)	1.99 (± 2.84)			
Week 72 (N = 30)	2.12 (± 4.03)			
Week 84 (N = 29)	6.36 (± 20.81)			
Week 96 (N = 27)	2.68 (± 4.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: C-reactive Protein (CRP): PsA Sub-population

End point title	C-reactive Protein (CRP): PsA Sub-population
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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. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: mg/L				
arithmetic mean (standard deviation)				
Baseline (N = 29)	3.19 (± 4.71)			
Week 4 (N = 29)	1.58 (± 1.73)			
Week 8 (N = 29)	1.41 (± 0.98)			
Week 12 (N = 28)	1.36 (± 0.75)			
Week 24 (N = 28)	2.11 (± 3.16)			
Week 36 (N = 27)	1.31 (± 0.81)			
Week 48 (N = 28)	1.35 (± 0.97)			
Week 60 (N = 25)	1.04 (± 0.12)			
Week 72 (N = 26)	2.08 (± 3.51)			
Week 84 (N = 26)	1.44 (± 0.97)			
Week 96 (N = 24)	1.58 (± 2.18)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pain Assessment

End point title	Pain Assessment
End point description: Pain Assessment was assessed by the subject's parent using a 21-circle VAS ranging from 0 to 10, with 0 = no pain and 10 = very severe pain. mITT population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Secondary
End point timeframe: Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 127)	5.06 (± 2.52)			
Week 4 (N = 126)	3.12 (± 2.25)			

Week 8 (N = 121)	2.58 (± 2.1)			
Week 12 (N = 123)	2.02 (± 1.89)			
Week 24 (N = 122)	1.64 (± 1.74)			
Week 36 (N = 120)	1.63 (± 1.94)			
Week 48 (N = 119)	1.51 (± 1.81)			
Week 60 (N = 116)	1.18 (± 1.46)			
Week 72 (N = 114)	1.14 (± 1.62)			
Week 84 (N = 112)	1.13 (± 1.67)			
Week 96 (N = 108)	0.91 (± 1.42)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pain Assessment: eoJIA Sub-population

End point title	Pain Assessment: eoJIA Sub-population
End point description:	
Pain Assessment was assessed by the subject's parent using a 21-circle VAS ranging from 0 to 10, with 0 = no pain and 10 = very severe pain. eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease that progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Secondary
End point timeframe:	
Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 60)	4.81 (± 2.56)			
Week 4 (N = 59)	2.64 (± 2.09)			
Week 8 (N = 56)	2.12 (± 1.97)			
Week 12 (N = 58)	1.69 (± 1.77)			
Week 24 (N = 58)	1.27 (± 1.66)			
Week 36 (N = 57)	1.43 (± 1.98)			
Week 48 (N = 57)	1.19 (± 1.77)			
Week 60 (N = 56)	1.19 (± 1.38)			
Week 72 (N = 55)	1.01 (± 1.52)			
Week 84 (N = 54)	0.91 (± 1.5)			
Week 96 (N = 53)	0.97 (± 1.52)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pain Assessment: ERA Sub-population

End point title	Pain Assessment: ERA Sub-population
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End point description:

Pain Assessment was assessed by the subject's parent using a 21-circle VAS ranging from 0 to 10, with 0 = no pain and 10 = very severe pain. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 38)	5.76 (± 2.51)			
Week 4 (N = 38)	3.82 (± 2.59)			
Week 8 (N = 36)	3.13 (± 2.42)			
Week 12 (N = 36)	2.54 (± 2.18)			
Week 24 (N = 36)	2.28 (± 1.89)			
Week 36 (N = 35)	1.87 (± 2.07)			
Week 48 (N = 34)	1.78 (± 1.72)			
Week 60 (N = 33)	1.17 (± 1.69)			
Week 72 (N = 32)	1.17 (± 1.69)			
Week 84 (N = 31)	1.08 (± 1.34)			
Week 96 (N = 30)	0.87 (± 1.21)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pain Assessment: PsA Sub-population

End point title	Pain Assessment: PsA Sub-population
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End point description:

Pain Assessment was assessed by the subject's parent using a 21-circle VAS ranging from 0 to 10, with 0 = no pain and 10 = very severe pain. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 29)	4.64 (± 2.31)			
Week 4 (N = 29)	3.19 (± 1.91)			
Week 8 (N = 29)	2.81 (± 1.74)			
Week 12 (N = 29)	2.03 (± 1.65)			
Week 24 (N = 28)	1.61 (± 1.51)			
Week 36 (N = 28)	1.71 (± 1.67)			
Week 48 (N = 28)	1.82 (± 1.95)			
Week 60 (N = 27)	1.19 (± 1.35)			
Week 72 (N = 27)	1.37 (± 1.74)			
Week 84 (N = 27)	1.61 (± 2.2)			
Week 96 (N = 25)	0.84 (± 1.48)			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Morning Stiffness

End point title	Duration of Morning Stiffness
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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). mITT population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Minutes				
arithmetic mean (standard deviation)				
Baseline (N = 127)	73.5 (± 100.61)			
Week 4 (N = 126)	29.86 (± 60)			

Week 8 (N = 121)	25.02 (± 75.32)			
Week 12 (N = 123)	13.29 (± 41.2)			
Week 24 (N = 122)	8.83 (± 23.41)			
Week 36 (N = 120)	6.76 (± 24.41)			
Week 48 (N = 119)	6.01 (± 23.94)			
Week 60 (N = 116)	7.28 (± 30.28)			
Week 72 (N = 113)	8.98 (± 30.67)			
Week 84 (N = 112)	8.4 (± 32.38)			
Week 96 (N = 109)	5.76 (± 21.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Morning Stiffness: eoJIA Sub-population

End point title	Duration of Morning Stiffness: eoJIA Sub-population
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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). eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease that progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Minutes				
arithmetic mean (standard deviation)				
Baseline (N = 60)	72.78 (± 97.24)			
Week 4 (N = 59)	20.46 (± 47.37)			
Week 8 (N = 56)	20.18 (± 70.7)			
Week 12 (N = 58)	9.05 (± 24.52)			
Week 24 (N = 58)	5.72 (± 18.85)			
Week 36 (N = 57)	2.49 (± 9.35)			
Week 48 (N = 57)	2.19 (± 6.61)			
Week 60 (N = 56)	2.41 (± 7.32)			
Week 72 (N = 54)	3.89 (± 15.16)			
Week 84 (N = 55)	2.64 (± 8.97)			
Week 96 (N = 54)	2.37 (± 12.42)			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Morning Stiffness: ERA Sub-population

End point title	Duration of Morning Stiffness: ERA Sub-population
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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). ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Minutes				
arithmetic mean (standard deviation)				
Baseline (N = 38)	89.29 (± 128.94)			
Week 4 (N = 38)	49.34 (± 78.73)			
Week 8 (N = 36)	44.03 (± 102.65)			
Week 12 (N = 36)	25.69 (± 67.57)			
Week 24 (N = 36)	15.69 (± 28.87)			
Week 36 (N = 35)	17.17 (± 41.01)			
Week 48 (N = 34)	13.38 (± 36.88)			
Week 60 (N = 33)	14.09 (± 42.21)			
Week 72 (N = 32)	16.25 (± 42.12)			
Week 84 (N = 30)	12.7 (± 36.16)			
Week 96 (N = 30)	10.67 (± 28.31)			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Morning Stiffness: PsA Sub-population

End point title	Duration of Morning Stiffness: PsA Sub-population
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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). PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Minutes				
arithmetic mean (standard deviation)				
Baseline (N = 29)	54.31 (± 54.16)			
Week 4 (N = 29)	23.45 (± 49.86)			
Week 8 (N = 29)	10.79 (± 24.55)			
Week 12 (N = 29)	6.38 (± 13.42)			
Week 24 (N = 28)	6.43 (± 23.17)			
Week 36 (N = 28)	2.43 (± 11.33)			
Week 48 (N = 28)	4.82 (± 25.51)			
Week 60 (N = 27)	9.07 (± 40.43)			
Week 72 (N = 27)	10.56 (± 36.7)			
Week 84 (N = 27)	15.37 (± 52.05)			
Week 96 (N = 25)	7.2 (± 27.43)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Inactive Disease Per Wallace 2004
Definition

End point title	Percentage of Subjects With Inactive Disease Per Wallace 2004 Definition
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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. mITT population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Percentage of subjects				
number (not applicable)				
Week 4 (N = 126)	2.4			
Week 8 (N = 121)	2.5			
Week 12 (N = 123)	12.2			
Week 24 (N = 121)	24.8			
Week 36 (N = 120)	25			
Week 48 (N = 118)	29.7			
Week 60 (N = 113)	33.6			
Week 72 (N = 111)	36			
Week 84 (N = 110)	34.5			
Week 96 (N = 106)	34			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Inactive Disease Per Wallace 2004
Definition: eoJIA Sub-population

End point title	Percentage of Subjects With Inactive Disease Per Wallace 2004 Definition: eoJIA Sub-population
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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.

eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease and had progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Percentage of subjects				
number (not applicable)				
Week 4 (N = 59)	5.1			
Week 8 (N = 56)	3.6			
Week 12 (N = 58)	12.1			
Week 24 (N = 57)	29.8			
Week 36 (N = 57)	35.1			
Week 48 (N = 56)	37.5			
Week 60 (N = 56)	48.2			
Week 72 (N = 54)	46.3			
Week 84 (N = 54)	44.4			
Week 96 (N = 53)	37.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Inactive Disease Per Wallace 2004 Definition: ERA Sub-population

End point title	Percentage of Subjects With Inactive Disease Per Wallace 2004 Definition: ERA Sub-population
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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.

ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; humanleukocyte antigen; Ar in male >6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Percentage of subjects				
number (not applicable)				
Week 4 (N = 38)	0			
Week 8 (N = 36)	2.8			
Week 12 (N = 36)	16.7			
Week 24 (N = 36)	25			

Week 36 (N = 35)	14.3			
Week 48 (N = 34)	23.5			
Week 60 (N = 30)	23.3			
Week 72 (N = 30)	33.3			
Week 84 (N = 29)	27.6			
Week 96 (N = 28)	28.6			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Inactive Disease Per Wallace 2004 Definition: PsA Sub-population

End point title	Percentage of Subjects With Inactive Disease Per Wallace 2004 Definition: PsA Sub-population
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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.

PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Percentage of subjects				
number (not applicable)				
Week 4 (N = 29)	0			
Week 8 (N = 29)	0			
Week 12 (N = 29)	6.9			
Week 24 (N = 28)	14.3			
Week 36 (N = 28)	17.9			
Week 48 (N = 28)	21.4			
Week 60 (N = 27)	14.8			
Week 72 (N=27)	18.5			
Week 84 (N = 27)	22.2			
Week 96 (N = 25)	32			

Statistical analyses

No statistical analyses for this end point

Secondary: Childhood Health Assessment Questionnaire (CHAQ) Score

End point title	Childhood Health Assessment Questionnaire (CHAQ) Score
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End point description:

CHAQ: parent-administered, valid assessment of functional disability, discomfort in pediatrics with rheumatic diseases. Parents report subjects'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. mITT population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 127)	0.8 (± 0.63)			
Week 4 (N = 126)	0.54 (± 0.55)			
Week 8 (N = 121)	0.42 (± 0.45)			
Week 12 (N = 123)	0.32 (± 0.4)			
Week 24 (N = 122)	0.28 (± 0.39)			
Week 36 (N = 120)	0.23 (± 0.39)			
Week 48 (N = 119)	0.24 (± 0.41)			
Week 60 (N = 116)	0.2 (± 0.37)			
Week 72 (N = 114)	0.17 (± 0.32)			
Week 84 (N = 113)	0.17 (± 0.35)			
Week 96 (N = 109)	0.16 (± 0.35)			

Statistical analyses

No statistical analyses for this end point

Secondary: Childhood Health Assessment Questionnaire (CHAQ) Score: eoJIA Sub-population

End point title	Childhood Health Assessment Questionnaire (CHAQ) Score: eoJIA Sub-population
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End point description:

CHAQ: parent-administered, valid assessment of functional disability, discomfort in pediatrics with rheumatic diseases. Parents report subjects'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. eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease that progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
End point timeframe:	
Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 60)	0.9 (± 0.68)			
Week 4 (N = 59)	0.64 (± 0.6)			
Week 8 (N = 56)	0.5 (± 0.54)			
Week 12 (N = 58)	0.4 (± 0.48)			
Week 24 (N = 58)	0.31 (± 0.43)			
Week 36 (N = 57)	0.26 (± 0.46)			
Week 48 (N = 57)	0.27 (± 0.48)			
Week 60 (N = 56)	0.25 (± 0.45)			
Week 72 (N = 55)	0.21 (± 0.37)			
Week 84 (N = 55)	0.21 (± 0.41)			
Week 96 (N = 54)	0.2 (± 0.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Childhood Health Assessment Questionnaire (CHAQ) Score: ERA Sub-population

End point title	Childhood Health Assessment Questionnaire (CHAQ) Score: ERA Sub-population
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End point description:

CHAQ: parent-administered, valid assessment of functional disability, discomfort in pediatrics with rheumatic diseases. Parents report subjects'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. ERA: subjects with Ar /enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 38)	0.72 (± 0.51)			
Week 4 (N = 38)	0.48 (± 0.56)			
Week 8 (N = 36)	0.4 (± 0.34)			
Week 12 (N = 36)	0.23 (± 0.27)			
Week 24 (N = 36)	0.27 (± 0.38)			
Week 36 (N = 35)	0.2 (± 0.32)			
Week 48 (N = 34)	0.18 (± 0.28)			
Week 60 (N = 33)	0.17 (± 0.29)			
Week 72 (N = 32)	0.13 (± 0.27)			
Week 84 (N = 31)	0.1 (± 0.22)			
Week 96 (N = 30)	0.08 (± 0.21)			

Statistical analyses

No statistical analyses for this end point

Secondary: Childhood Health Assessment Questionnaire (CHAQ) Score: PsA Sub-population

End point title	Childhood Health Assessment Questionnaire (CHAQ) Score: PsA Sub-population
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End point description:

CHAQ: parent-administered, valid assessment of functional disability, discomfort in pediatrics with rheumatic diseases. Parents report subjects'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. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Secondary
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 29)	0.68 (± 0.63)			
Week 4 (N = 29)	0.42 (± 0.41)			
Week 8 (N = 29)	0.3 (± 0.34)			
Week 12 (N = 29)	0.29 (± 0.35)			

Week 24 (N = 28)	0.26 (± 0.32)			
Week 36 (N = 28)	0.21 (± 0.32)			
Week 48 (N = 28)	0.24 (± 0.38)			
Week 60 (N = 27)	0.13 (± 0.25)			
Week 72 (N = 27)	0.15 (± 0.29)			
Week 84 (N = 27)	0.18 (± 0.35)			
Week 96 (N = 25)	0.18 (± 0.36)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Tender Enthesal Assessment for ERA Sub-population

End point title	Tender Enthesal Assessment for ERA Sub-population
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End point description:

Tender enthesal assessment: Entheses were assessed and coded as: 1= any tenderness, 0= no tenderness, NE= not evaluable. Total number of tender entheses: 66*(total number of tender entheses with counts > 0)/number of non-missing tender entheses. If >33 tender enthesal counts were missing, total number of tender entheses was defined as missing. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Tender entheses				
arithmetic mean (standard deviation)				
Baseline (N = 38)	5.87 (± 9.42)			
Week 4 (N = 38)	4.68 (± 11.81)			
Week 8 (N = 36)	2.06 (± 5.79)			
Week 12 (N = 36)	1.81 (± 6.15)			
Week 24 (N = 36)	1.89 (± 6.89)			
Week 36 (N = 35)	2.03 (± 5.7)			
Week 48 (N = 34)	1.32 (± 3.76)			
Week 60 (N = 33)	0.97 (± 2.98)			
Week 72 (N = 32)	0.56 (± 1.29)			
Week 84 (N = 31)	0.77 (± 2)			
Week 96 (N = 30)	0.33 (± 1.03)			

Statistical analyses

Other pre-specified: Overall Back Pain Score for ERA Sub-population

End point title	Overall Back Pain Score for ERA Sub-population
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. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Other pre-specified
End point timeframe:	
Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: mm				
arithmetic mean (standard deviation)				
Baseline (N = 37)	25.94 (± 28)			
Week 4 (N = 38)	14.24 (± 19.87)			
Week 8 (N = 36)	12.94 (± 22.6)			
Week 12 (N = 36)	11.83 (± 18.22)			
Week 24 (N = 36)	9.81 (± 17.23)			
Week 36 (N = 35)	10.16 (± 19.2)			
Week 48 (N = 34)	8.62 (± 15.76)			
Week 60 (N = 32)	5.13 (± 12.28)			
Week 72 (N = 32)	6.03 (± 14.67)			
Week 84 (N = 31)	5.03 (± 8.4)			
Week 96 (N = 30)	2.37 (± 4.51)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Nocturnal Back Pain Score for ERA Sub-population

End point title	Nocturnal Back Pain Score for ERA Sub-population
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. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Other pre-specified
End point timeframe:	
Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: mm				
arithmetic mean (standard deviation)				
Baseline (N = 38)	16.37 (\pm 27.76)			
Week 4 (N = 38)	8.58 (\pm 19.31)			
Week 8 (N = 36)	7.82 (\pm 18.34)			
Week 12 (N = 36)	5.81 (\pm 11.74)			
Week 24 (N = 36)	5.31 (\pm 15.17)			
Week 36 (N = 35)	7.54 (\pm 17.66)			
Week 48 (N = 34)	5.85 (\pm 13.82)			
Week 60 (N = 32)	3.34 (\pm 13.36)			
Week 72 (N = 32)	6.47 (\pm 19.64)			
Week 84 (N = 31)	2.66 (\pm 6.86)			
Week 96 (N = 30)	2.17 (\pm 3.5)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Modified Schober's Test for ERA Sub-population

End point title	Modified Schober's Test for ERA Sub-population
End point description:	
<p>Modified Schober's Test: A mark was placed in the midpoint of a line that joined the posterior superior iliac spines. Another mark was placed 10 centimeter (cm) above the first. The subject then bent maximally forward with the knees fully extended. The distance between the two marks was then re-measured. The full measurement between the two lines was recorded to the nearest tenth of a centimeter.</p> <p>ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).</p>	
End point type	Other pre-specified
End point timeframe:	
Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: cm				
arithmetic mean (standard deviation)				
Baseline (N = 37)	5.03 (± 1.94)			
Week 4 (N = 38)	5.24 (± 1.94)			
Week 8 (N = 36)	5.12 (± 2.36)			
Week 12 (N = 36)	5.45 (± 1.98)			
Week 24 (N = 36)	5.35 (± 2.1)			
Week 36 (N = 35)	5.49 (± 2.1)			
Week 48 (N = 34)	5.38 (± 1.59)			
Week 60 (N = 33)	5.33 (± 1.71)			
Week 72 (N = 32)	5.27 (± 1.59)			
Week 84 (N = 30)	5.47 (± 1.68)			
Week 96 (N = 30)	5.33 (± 1.65)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Body Surface Area (BSA) Affected by Psoriasis for PsA Sub-population

End point title	Percentage of Body Surface Area (BSA) Affected by Psoriasis for PsA Sub-population
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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% 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. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Percentage of BSA				
arithmetic mean (standard deviation)				
Baseline (N = 29)	9.83 (± 13.61)			
Week 4 (N = 29)	6.81 (± 9.02)			
Week 8 (N = 29)	4.67 (± 7.68)			
Week 12 (N = 29)	3.49 (± 5.66)			

Week 24 (N = 28)	2.36 (± 4.24)			
Week 36 (N = 28)	2.91 (± 8.7)			
Week 48 (N = 28)	3.12 (± 8.13)			
Week 60 (N = 27)	1.48 (± 2.38)			
Week 72 (N = 27)	1.53 (± 2.17)			
Week 84 (N = 27)	1.56 (± 2.27)			
Week 96 (N = 25)	1.14 (± 2.12)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Physician's Global Assessment (PGA) of Psoriasis for PsA Sub-population

End point title	Physician's Global Assessment (PGA) of Psoriasis for PsA Sub-population
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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 subjects who were scored as a 0 or 1. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (N = 29)	1.76 (± 1.46)			
Week 4 (N = 29)	1.41 (± 1.18)			
Week 8 (N = 29)	1.07 (± 1.03)			
Week 12 (N = 28)	0.82 (± 0.72)			
Week 24 (N = 28)	0.61 (± 0.69)			
Week 36 (N = 28)	0.61 (± 0.88)			
Week 48 (N = 28)	0.75 (± 0.89)			
Week 60 (N = 27)	0.78 (± 0.97)			
Week 72 (N = 26)	0.65 (± 0.94)			
Week 84 (N = 27)	0.56 (± 0.85)			
Week 96 (N = 25)	0.48 (± 0.82)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of subjects With Adverse Events (AEs)

End point title	Number of subjects With Adverse Events (AEs)
End point description: An AE was any untoward medical occurrence attributed to study drug in a subject who received study drug. Number of subjects reporting adverse events included medically important infections, infections considered preventable by vaccination, injection site reactions (ISRs), malignancies, AEs, excluding infections and injection site reactions, infections and serious adverse events (SAEs) including infections. Safety population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Other pre-specified
End point timeframe: Week 12, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Subjects				
Medically important infections	11			
Vaccine preventable infections	8			
ISRs	16			
Malignancies	0			
Infections	96			
Infection and ISRs excluded	93			
Serious AE: Infection	11			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Subjects With Adverse Events (AEs): eoJIA Subpopulation

End point title	Number of Subjects With Adverse Events (AEs): eoJIA Subpopulation
End point description: An AE was any untoward medical occurrence attributed to study drug in a subject who received study drug. Number of subjects reporting AEs included medically important infections, infections considered preventable by vaccination, ISRs, malignancies, AEs, excluding infections and injection site reactions, infections and serious adverse events including infections. eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease that progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Other pre-specified
End point timeframe: Week 12, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Subjects				
Medically important infections	4			
Vaccine preventable infections	6			
ISRs	8			
Malignancies	0			
Infections	48			
Infection and ISRs excluded	44			
Serious AE: Infection	4			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Subjects With Adverse Events (AEs): ERA Sub-population

End point title	Number of Subjects With Adverse Events (AEs): ERA Sub-population
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End point description:

An AE was any untoward medical occurrence attributed to study drug in a subject who received study drug. Number of subjects reporting AEs included medically important infections, infections considered preventable by vaccination, ISRs, malignancies, AEs, excluding infections and injection site reactions, infections and serious adverse events including infections. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen-B27;Ar in male >6yrs; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
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End point timeframe:

Week 12, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Subjects				
Medically important infections	4			
Vaccine preventable infections	1			
ISRs	6			
Malignancies	0			
Infections	28			
Infection and ISRs excluded	30			
Serious AE: Infection	4			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Subjects With Adverse Events (AEs): PsA Sub-population

End point title	Number of Subjects With Adverse Events (AEs): PsA Sub-population
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End point description:

An AE was any untoward medical occurrence attributed to study drug in a subject who received study drug. Number of subjects reporting AEs included medically important infections, infections considered preventable by vaccination, ISRs, malignancies, AEs, excluding infections and injection site reactions, infections and serious adverse events including infections. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
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End point timeframe:

Week 12, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Subjects				
Medically important infections	3			
Vaccine preventable infections	1			
ISRs	2			
Malignancies	0			
Infections	20			
Infection and ISRs excluded	19			
Serious AE: Infection	3			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Tanner Assessment Score by Age Group

End point title	Tanner Assessment Score by Age Group
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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). Safety population: subjects who received at least 1 dose of study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
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End point timeframe:

Baseline, Week 12, Week 48, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline: 2 to 17 years (N = 126)	3.08 (± 1.59)			
Week 12: 2 to 17 years (N = 122)	3.18 (± 1.63)			
Week 48: 2 to 17 years (N = 118)	3.34 (± 1.61)			
Week 96: 2 to 17 years (N = 106)	3.57 (± 1.61)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Tanner Assessment Score by Age Group for eoJIA Sub-population

End point title	Tanner Assessment Score by Age Group for eoJIA Sub-population
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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). eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease that progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
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End point timeframe:

Baseline, Week 12, Week 48, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline: 2 to 4 years (N=14)	1 (± 0)			
Baseline: 5 to 11 years (N=23)	1.16 (± 0.44)			
Baseline: 12 to 17 years (N=22)	3.94 (± 0.97)			
Baseline: 2 to 17 years (N=59)	2.16 (± 1.53)			
Week 12: 2 to 4 years (N=14)	1 (± 0)			
Week 12: 5 to 11 years (N=22)	1.17 (± 0.45)			
Week 12: 12 to 17 years (N=21)	4.02 (± 0.95)			
Week 12: 2 to 17 years (N=57)	2.18 (± 1.56)			
Week 48: 2 to 4 years (n=13)	1 (± 0)			
Week 48: 5 to 11 years (N=22)	1.3 (± 0.63)			
Week 48: 12 to 17 years (N=21)	4.35 (± 0.83)			
Week 48: 2 to 17 years (N=56)	2.37 (± 1.67)			
Week 96: 2 to 4 years (N=13)	1 (± 0)			

Week 96: 5 to 11 years (N=19)	1.67 (± 1.08)			
Week 96: 12 to 17 years (N=20)	4.53 (± 0.62)			
Week 96: 2 to 17 years (N=52)	2.6 (± 1.73)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Tanner Assessment Score by Age Group for ERA Sub-population

End point title	Tanner Assessment Score by Age Group for ERA Sub-population
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). ERA: subjects with Ar/enthesitis, any 2:sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Other pre-specified
End point timeframe:	
Baseline, Week 12, Week 48, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline: 12 to 17 years (N = 38)	3.87 (± 1.07)			
Week 12: 12 to 17 years (N = 36)	4.09 (± 1.04)			
Week 48: 12 to 17 years (N = 34)	4.24 (± 0.84)			
Week 96: 12 to 17 years (N = 30)	4.51 (± 0.66)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Tanner Assessment Score by Age Group for PsA Sub-population

End point title	Tanner Assessment Score by Age Group for PsA Sub-population
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). PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96	

weeks).

End point type	Other pre-specified
End point timeframe:	
Baseline, Week 12, Week 48, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline: 12 to 17 years (N = 29)	3.93 (\pm 1.22)			
Week 12: 12 to 17 years (N = 29)	4.02 (\pm 1.19)			
Week 48: 12 to 17 years (N = 28)	4.2 (\pm 0.95)			
Week 96: 12 to 17 years (N = 24)	4.51 (\pm 0.69)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Height z-Score by Age Group

End point title	Height z-Score by Age Group
End point description:	
Standing height was taken as a mean of 3 consecutive measurements using a wall mounted stadiometer. Z-Score was a statistical measure to evaluate how a single data point compares to a standard. It described whether a mean was above or below the standard and how unusual the measurement is with range from -3 to +3; 0 =same mean, >0 a greater mean, and <0 a lesser mean than the standard. Growth parameters were compared to a standard defined by Centers for Disease Control's growth charts. Safety population: subjects who received at least 1 dose of study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Other pre-specified
End point timeframe:	
Baseline, Week 12, Week 48, Week 72, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: z-score				
arithmetic mean (standard deviation)				
Baseline: 2 to 17 years (N = 125)	0.19 (\pm 1.07)			
Week 12: 2 to 17 years (N = 123)	0.31 (\pm 0.98)			
Week 48: 2 to 17 years (N = 118)	0.34 (\pm 1.02)			
Week 72: 2 to 17 years (N = 114)	0.41 (\pm 0.97)			
Week 96: 2 to 17 years (N = 109)	0.39 (\pm 0.99)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Height z-Score by Age Group for eoJIA Sub-population

End point title	Height z-Score by Age Group for eoJIA Sub-population
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End point description:

Standing height was taken as a mean of 3 consecutive measurements using a wall mounted stadiometer. Z-Score was a statistical measure to evaluate how a single data point compares to a standard. It described whether a mean was above or below the standard and how unusual the measurement is with range from -3 to +3; 0 =same mean, >0 a greater mean, and <0 a lesser mean than the standard. Growth parameters were compared to a standard defined by Centers for Disease Control's growth charts. eoJIA sub-population: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease and had progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
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End point timeframe:

Baseline, Week 12, Week 48, Week 72, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: z-score				
arithmetic mean (standard deviation)				
Baseline: 2 to 4 years (N=15)	-0.24 (± 1.32)			
Baseline: 5 to 11 years (N=22)	0.2 (± 1.35)			
Baseline: 12 to 17 years (N=21)	0.13 (± 0.84)			
Baseline: 2 to 17 years (N=58)	0.06 (± 1.17)			
Week 12: 2 to 4 years (N=15)	0.17 (± 0.97)			
Week 12: 5 to 11 years (N=22)	0.28 (± 1.23)			
Week 12: 12 to 17 years (N=21)	0.16 (± 0.83)			
Week 12: 2 to 17 years (N=58)	0.21 (± 1.02)			
Week 48: 2 to 4 years (N=14)	0.37 (± 1.06)			
Week 48: 5 to 11 years (N=21)	0.3 (± 1.3)			
Week 48: 12 to 17 years (N=21)	0.18 (± 0.87)			
Week 48: 2 to 17 years (N=56)	0.27 (± 1.08)			
Week 72: 2 to 4 years (N=14)	0.39 (± 0.99)			
Week 72: 5 to 11 years (N=21)	0.43 (± 1.11)			
Week 72: 12 to 17 years (N=20)	0.2 (± 0.87)			
Week 72: 2 to 17 years (N=55)	0.34 (± 0.98)			
Week 96: 2 to 4 years (N=14)	0.34 (± 0.99)			
Week 96: 5 to 11 years (N=20)	0.46 (± 1.15)			
Week 96: 12 to 17 years (N=20)	0.17 (± 0.89)			
Week 96: 2 to 17 years (N=54)	0.32 (± 1.01)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Height z-Score by Age Group for ERA Sub-population

End point title	Height z-Score by Age Group for ERA Sub-population
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End point description:

Standing height was taken as a mean of 3 consecutive measurements using a wall mounted stadiometer. Z-Score was a statistical measure to evaluate how a single data point compares to a standard. It described whether a mean was above or below the standard and how unusual the measurement is with range from -3 to +3; 0 =same mean, >0 a greater mean, and <0 a lesser mean than the standard. Growth parameters were compared to a standard defined by Centers for Disease Control's growth charts. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
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End point timeframe:

Baseline, Week 12, Week 48, Week 72, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: z-score				
arithmetic mean (standard deviation)				
Baseline: 12 to 17 years (N = 38)	0.24 (± 0.89)			
Week 12: 12 to 17 years (N = 36)	0.35 (± 0.86)			
Week 48: 12 to 17 years (N = 34)	0.36 (± 0.85)			
Week 72: 12 to 17 years (N = 32)	0.46 (± 0.84)			
Week 96: 12 to 17 years (N = 30)	0.43 (± 0.86)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Height z-Score by Age Group for PsA Sub-population

End point title	Height z-Score by Age Group for PsA Sub-population
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End point description:

Standing height was taken as a mean of 3 consecutive measurements using a wall mounted stadiometer. Z-Score was a statistical measure to evaluate how a single data point compares to a standard. It described whether a mean was above or below the standard and how unusual the measurement is with range from -3 to +3; 0 =same mean, >0 a greater mean, and <0 a lesser mean than the standard. Growth parameters were compared to a standard defined by Centers for Disease

Control's growth charts. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
End point timeframe:	
Baseline, Week 12, Week 48, Week 72, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: z-score				
arithmetic mean (standard deviation)				
Baseline: 12 to 17 years (N = 29)	0.41 (\pm 1.06)			
Week 12: 12 to 17 years (N = 29)	0.46 (\pm 1.05)			
Week 48: 12 to 17 years (N = 28)	0.47 (\pm 1.11)			
Week 72: 12 to 17 years (N = 27)	0.51 (\pm 1.1)			
Week 96: 12 to 17 years (N = 25)	0.48 (\pm 1.11)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Weight z-Scores by Age Group

End point title	Weight z-Scores by Age Group
End point description:	
Weight was taken as a mean of 3 consecutive measurements using a medical electronic scale. Z-Score was a statistical measure to evaluate how a single data point compares to a standard. It described whether a mean was above or below the standard and how unusual the measurement is with range from -3 to +3; 0 =same mean, >0 a greater mean, and <0 a lesser mean than the standard. Growth parameters were compared to a standard defined by Centers for Disease Control's growth charts. Safety population: subjects who received at least 1 dose of study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Other pre-specified
End point timeframe:	
Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96.	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: z-score				
arithmetic mean (standard deviation)				
Baseline: 2 to 17 years (N = 127)	0.17 (\pm 1.02)			
Week 4: 2 to 17 years (N = 126)	0.18 (\pm 1.02)			
Week 8: 2 to 17 years (N = 121)	0.23 (\pm 1.02)			

Week 12: 2 to 17 years (N = 123)	0.22 (\pm 1)			
Week 24: 2 to 17 years (N = 122)	0.25 (\pm 0.99)			
Week 36: 2 to 17 years (N = 120)	0.26 (\pm 0.97)			
Week 48: 2 to 17 years (N = 118)	0.25 (\pm 0.97)			
Week 60: 2 to 17 years (N = 116)	0.24 (\pm 0.95)			
Week 72: 2 to 17 years (N = 114)	0.29 (\pm 0.91)			
Week 84: 2 to 17 years (N = 113)	0.27 (\pm 0.93)			
Week 96: 2 to 17 years (N = 109)	0.25 (\pm 0.93)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Weight z-Scores by Age Group for eoJIA Sub-population

End point title	Weight z-Scores by Age Group for eoJIA Sub-population
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End point description:

Weight was taken as a mean of 3 consecutive measurements using a medical electronic scale. Z-Score was a statistical measure to evaluate how a single data point compares to a standard. It described whether a mean was above or below the standard and how unusual the measurement is with range from -3 to +3; 0 =same mean, >0 a greater mean, and <0 a lesser mean than the standard. Growth parameters were compared to a standard defined by Centers for Disease Control's growth charts. eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease and had progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: z-score				
arithmetic mean (standard deviation)				
Baseline: 2 to 4 years (N=15)	-0.5 (\pm 0.98)			
Baseline: 5 to 11 years (N=23)	0.15 (\pm 1.33)			
Baseline: 12 to 17 years (N=22)	0.4 (\pm 0.72)			
Baseline: 2 to 17 years (N=60)	0.08 (\pm 1.1)			
Week 4: 2 to 4 years (N=15)	-0.54 (\pm 1.13)			
Week 4: 5 to 11 years (N=23)	0.17 (\pm 1.34)			
Week 4: 12 to 17 years (N=21)	0.38 (\pm 0.69)			
Week 4: 2 to 17 years (N=59)	0.06 (\pm 1.13)			
Week 8: 2 to 4 years (N=14)	-0.48 (\pm 1.25)			
Week 8: 5 to 11 years (N=21)	0.3 (\pm 1.3)			
Week 8: 12 to 17 years (N=21)	0.4 (\pm 0.72)			
Week 8: 2 to 17 years (N=56)	0.14 (\pm 1.14)			
Week 12: 2 to 4 years (n=15)	-0.35 (\pm 1.09)			
Week 12: 5 to 11 years (N=22)	0.22 (\pm 1.35)			

Week 12: 12 to 17 years (N=21)	0.41 (± 0.72)			
Week 12: 2 to 17 years (N=58)	0.14 (± 1.11)			
Week 24: 2 to 4 years (N=15)	-0.21 (± 1.1)			
Week 24: 5 to 11 years (N=22)	0.21 (± 1.32)			
Week 24: 12 to 17 years (N=21)	0.46 (± 0.69)			
Week 24: 2 to 17 years (N=58)	0.19 (± 1.08)			
Week 36: 2 to 4 years (N=14)	-0.25 (± 1.14)			
Week 36: 5 to 11 years (N=22)	0.27 (± 1.25)			
Week 36: 12 to 17 years (N=21)	0.39 (± 0.7)			
Week 36: 2 to 17 years (N=57)	0.18 (± 1.06)			
Week 48: 2 to 4 years (N=14)	-0.28 (± 1.15)			
Week 48: 5 to 11 years (N=21)	0.21 (± 1.24)			
Week 48: 12 to 17 years (N=21)	0.4 (± 0.65)			
Week 48: 2 to 17 years (N=56)	0.16 (± 1.05)			
Week 60: 2 to 4 years (N=14)	-0.18 (± 1.15)			
Week 60: 5 to 11 years (N=22)	0.23 (± 1.24)			
Week 60: 12 to 17 years (N=20)	0.31 (± 0.62)			
Week 60: 2 to 17 years (N=56)	0.16 (± 1.04)			
Week 72: 2 to 4 years (N=14)	-0.09 (± 1.12)			
Week 72: 5 to 11 years (N=21)	0.43 (± 1.13)			
Week 72: 12 to 17 years (N=20)	0.29 (± 0.67)			
Week 72: 2 to 17 years (N=55)	0.25 (± 0.99)			
Week 84: 2 to 4 years (N=14)	-0.1 (± 1.13)			
Week 84: 5 to 11 years (N=21)	0.42 (± 1.15)			
Week 84: 12 to 17 years (N=20)	0.23 (± 0.74)			
Week 84: 2 to 17 years (N=55)	0.22 (± 1.02)			
Week 96: 2 to 4 years (N=14)	-0.14 (± 1.18)			
Week 96: 5 to 11 years (N=20)	0.49 (± 1.11)			
Week 96: 12 to 17 years (N=20)	0.16 (± 0.76)			
Week 96: 2 to 17 years (N=54)	0.2 (± 1.03)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Weight z-Scores by Age Group for ERA Sub-population

End point title	Weight z-Scores by Age Group for ERA Sub-population
End point description:	
<p>Weight was taken as a mean of 3 consecutive measurements using a medical electronic scale. Z-Score was a statistical measure to evaluate how a single data point compares to a standard. It described whether a mean was above or below the standard and how unusual the measurement is with range from -3 to +3; 0 =same mean, >0 a greater mean, and <0 a lesser mean than the standard. Growth parameters were compared to a standard defined by Centers for Disease Control's growth charts. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).</p>	
End point type	Other pre-specified
End point timeframe:	
Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: z-score				
arithmetic mean (standard deviation)				
Baseline: 12 to 17 years (N = 38)	-0.05 (± 0.74)			
Week 4: 12 to 17 years (N = 38)	0 (± 0.72)			
Week 8: 12 to 17 years (N = 36)	0.04 (± 0.68)			
Week 12: 12 to 17 years (N = 36)	0 (± 0.65)			
Week 24: 12 to 17 years (N = 36)	0.01 (± 0.68)			
Week 36: 12 to 17 years (N = 35)	0.03 (± 0.68)			
Week 48: 12 to 17 years (N = 34)	0.04 (± 0.7)			
Week 60: 12 to 17 years (N = 33)	0.08 (± 0.67)			
Week 72: 12 to 17 years (N = 32)	0.12 (± 0.65)			
Week 84: 12 to 17 years (N = 31)	0.07 (± 0.67)			
Week 96: 12 to 17 years (N = 30)	0.06 (± 0.63)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Weight z-Scores by Age Group for PsA Sub-population

End point title	Weight z-Scores by Age Group for PsA Sub-population
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End point description:

Weight was taken as a mean of 3 consecutive measurements using a medical electronic scale. Z-Score was a statistical measure to evaluate how a single data point compares to a standard. It described whether a mean was above or below the standard and how unusual the measurement is with range from -3 to +3; 0 =same mean, >0 a greater mean, and <0 a lesser mean than the standard. Growth parameters were compared to a standard defined by Centers for Disease Control's growth charts. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
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End point timeframe:

Baseline, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: z-score				
arithmetic mean (standard deviation)				
Baseline: 12 to 17 years (N = 29)	0.63 (± 1.05)			
Week 4: 12 to 17 years (N = 29)	0.66 (± 1.01)			

Week 8: 12 to 17 years (N = 29)	0.64 (\pm 1.04)			
Week 12: 12 to 17 years (N = 29)	0.63 (\pm 1.04)			
Week 24: 12 to 17 years (N = 28)	0.66 (\pm 1.04)			
Week 36: 12 to 17 years (N = 28)	0.69 (\pm 0.97)			
Week 48: 12 to 17 years (N = 28)	0.7 (\pm 0.96)			
Week 60: 12 to 17 years (N = 27)	0.61 (\pm 1)			
Week 72: 12 to 17 years (N = 27)	0.57 (\pm 0.97)			
Week 84: 12 to 17 years (N = 27)	0.59 (\pm 0.94)			
Week 96: 12 to 17 years (N = 25)	0.59 (\pm 0.96)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Body Mass Index (BMI) z-Score by Age Group

End point title	Body Mass Index (BMI) z-Score by Age Group
End point description:	
BMI was used to measure body fat based on height and weight. It was calculated by body weight (kg)/height (m) squared. Z-Score was a statistical measure to evaluate how a single data point compares to a standard. It described whether a mean was above or below the standard and how unusual the measurement is with range from -3 to +3; 0 =same mean, >0 a greater mean, and <0 a lesser mean than the standard. Growth parameters were compared to a standard defined by Centers for Disease Control's growth charts. Safety population: subjects who received at least 1 dose of study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Other pre-specified
End point timeframe:	
Baseline, Week 12, Week 48, Week 72, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: z-score				
arithmetic mean (standard deviation)				
Baseline: 2 to 17 years (N = 125)	0.03 (\pm 1.17)			
Week 12: 2 to 17 years (N = 123)	0.03 (\pm 1.15)			
Week 48: 2 to 17 years (N = 118)	0.05 (\pm 1.11)			
Week 72: 2 to 17 years (N = 114)	0.07 (\pm 1.03)			
Week 96: 2 to 17 years (N = 109)	0.04 (\pm 1.06)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Body Mass Index (BMI) z-Score by Age Group for eoJIA Sub-population

End point title	Body Mass Index (BMI) z-Score by Age Group for eoJIA Sub-population
End point description:	
BMI was used to measure body fat based on height and weight. It was calculated by body weight (kg)/height (m) squared. Z-Score was a statistical measure to evaluate how a single data point compares to a standard. It described whether a mean was above or below the standard and how unusual the measurement is with range from -3 to +3; 0 =same mean, >0 a greater mean, and <0 a lesser mean than the standard. Growth parameters were compared to a standard defined by Centers for Disease Control's growth charts. eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease and had progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Other pre-specified
End point timeframe:	
Baseline, Week 12, Week 48, Week 72, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: z-score				
arithmetic mean (standard deviation)				
Baseline: 2 to 4 years (N=15)	-0.6 (± 1.7)			
Baseline: 5 to 11 years (N=22)	0.03 (± 1.28)			
Baseline: 12 to 17 years (N=21)	0.4 (± 0.72)			
Baseline: 2 to 17 years (N=58)	0 (± 1.28)			
Week 12: 2 to 4 years (N=15)	-0.78 (± 1.64)			
Week 12: 5 to 11 years (N=22)	0.21 (± 1.13)			
Week 12: 12 to 17 years (N=21)	0.38 (± 0.73)			
Week 12: 2 to 17 years (N=58)	0.01 (± 1.25)			
Week 48: 2 to 4 years (N=14)	-0.85 (± 1.69)			
Week 48: 5 to 11 years (N=21)	0.18 (± 0.96)			
Week 48: 12 to 17 years (N=21)	0.34 (± 0.68)			
Week 48: 2 to 17 years (N=56)	-0.02 (± 1.19)			
Week 72: 2 to 4 years (N=14)	-0.48 (± 1.46)			
Week 72: 5 to 11 years (N=21)	0.37 (± 0.97)			
Week 72: 12 to 17 years (N=20)	0.2 (± 0.73)			
Week 72: 2 to 17 years (N=55)	0.09 (± 1.08)			
Week 96: 2 to 4 years (N=14)	-0.5 (± 1.55)			
Week 96: 5 to 11 years (N=20)	0.44 (± 0.9)			
Week 96: 12 to 17 years (N=20)	0.05 (± 0.83)			
Week 96: 2 to 17 years (N=54)	0.05 (± 1.13)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Body Mass Index (BMI) z-Score by Age Group for ERA Sub-population

End point title	Body Mass Index (BMI) z-Score by Age Group for ERA Sub-population
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End point description:

BMI was used to measure body fat based on height and weight. It was calculated by body weight (kg)/height (m) squared. Z-Score was a statistical measure to evaluate how a single data point compares to a standard. It described whether a mean was above or below the standard and how unusual the measurement is with range from -3 to +3; 0 =same mean, >0 a greater mean, and <0 a lesser mean than the standard. Growth parameters were compared to a standard defined by Centers for Disease Control's growth charts. ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
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End point timeframe:

Baseline, Week 12, Week 48, Week 72, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: z-score				
arithmetic mean (standard deviation)				
Baseline: 12 to 17 years (N = 38)	-0.29 (± 0.87)			
Week 12: 12 to 17 years (N = 36)	-0.31 (± 0.86)			
Week 48: 12 to 17 years (N = 34)	-0.27 (± 0.91)			
Week 72: 12 to 17 years (N = 32)	-0.23 (± 0.87)			
Week 96: 12 to 17 years (N = 30)	-0.29 (± 0.84)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Body Mass Index (BMI) z-Score by Age Group for PsA Sub-population

End point title	Body Mass Index (BMI) z-Score by Age Group for PsA Sub-population
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End point description:

BMI was used to measure body fat based on height and weight. It was calculated by body weight (kg)/height (m) squared. Z-Score was a statistical measure to evaluate how a single data point compares to a standard. It described whether a mean was above or below the standard and how unusual the measurement is with range from -3 to +3; 0 =same mean, >0 a greater mean, and <0 a lesser mean than the standard. Growth parameters were compared to a standard defined by Centers for Disease Control's growth charts. PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
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End point timeframe:

Baseline, Week 12, Week 48, Week 72, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: z-score				
arithmetic mean (standard deviation)				
Baseline: 12 to 17 years (N = 29)	0.51 (± 1.17)			
Week 12: 12 to 17 years (N = 29)	0.49 (± 1.14)			
Week 48: 12 to 17 years (N = 28)	0.55 (± 1.01)			
Week 72: 12 to 17 years (N = 27)	0.37 (± 1.04)			
Week 96: 12 to 17 years (N = 25)	0.4 (± 1.06)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Subjects With Anti-etanercept Antibodies

End point title	Number of Subjects With Anti-etanercept Antibodies
End point description:	
Safety population included all subjects who received at least 1 dose of the study medication. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).	
End point type	Other pre-specified
End point timeframe:	
Baseline up to Week 12, Week 48, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Subjects				
Overall (N=127)	26			
Week 12 (N=120)	6			
Week 48 (N=116)	14			
Week 96 (N=105)	14			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Subjects With Anti-etanercept Antibodies: eoJIA Sub-population

End point title	Number of Subjects With Anti-etanercept Antibodies: eoJIA Sub-population
End point description:	
eoJIA: subjects with arthritis affecting 1 to 4 joints during the first 6 months of the disease that progressed to affect more than 4 joints after the first 6 months of disease. Data are presented for Part 1	

(up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
End point timeframe:	
Baseline up to Week 12, Week 48, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Subjects				
Overall (N=60)	11			
Week 12 (N=56)	0			
Week 48 (N=55)	7			
Week 96 (N=52)	7			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Subjects With Anti-etanercept Antibodies: ERA Sub-population

End point title	Number of Subjects With Anti-etanercept Antibodies: ERA Sub-population
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End point description:

ERA: subjects with Ar/enthesitis, any 2: sacroiliac joint tenderness/Ifm lumbosacral pain history; ankylosing spondylitis, ERA, sacroiliitis with Ifm bowel disease, Reiter's syndrome history; human leukocyte antigen; Ar in male >6years; AAU/AAU in first-degree relative. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
End point timeframe:	
Baseline up to Week 12, Week 48, Week 96	

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Subjects				
Overall (N=38)	9			
Week 12 (N=36)	4			
Week 48 (N=34)	4			
Week 96 (N=29)	3			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Subjects With Anti-etanercept Antibodies: PsA Sub-population

End point title	Number of Subjects With Anti-etanercept Antibodies: PsA Sub-population
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End point description:

PsA: subjects with 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. Data are presented for Part 1 (up to 12 weeks) and Part 2 (up to 96 weeks).

End point type	Other pre-specified
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End point timeframe:

Baseline up to Week 12, Week 48, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Subjects				
Overall (N=29)	6			
Week 12 (N=28)	2			
Week 48 (N=27)	3			
Week 96 (N=24)	4			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Subjects With Neutralizing Anti-etanercept Antibodies

End point title	Number of Subjects With Neutralizing Anti-etanercept Antibodies
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End point description:

Safety population included all subjects who received at least 1 dose of the study medication.

End point type	Other pre-specified
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End point timeframe:

Baseline up to Week 12, Week 48, Week 96

End point values	Etanercept			
Subject group type	Reporting group			
Number of subjects analysed	127			
Units: Subjects	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Screening up to Week 96

Adverse event reporting additional description:

The same event may appear as both an AE and a Serious Adverse Event (SAE). However, what is presented are distinct events. An event may be categorized as serious in one subject and as nonserious in another subject, or one subject may have experienced both a serious and nonserious event during the study.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	15.0
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Reporting groups

Reporting group title	Etanercept
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Reporting group description:

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

Serious adverse events	Etanercept		
Total subjects affected by serious adverse events			
subjects affected / exposed	24 / 127 (18.90%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Cartilage injury			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Concussion			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Forearm fracture			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fractured coccyx			

subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tendon injury			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Phimosis			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Adenoidectomy			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Crohn's disease			

subjects affected / exposed	1 / 127 (0.79%)		
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 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Attention deficit/hyperactivity disorder			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Juvenile arthritis			
subjects affected / exposed	2 / 127 (1.57%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Acute tonsillitis			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchopneumonia			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			

subjects affected / exposed	2 / 127 (1.57%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal infection			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Helicobacter gastritis			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pharyngitis			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelocystitis			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	1 / 127 (0.79%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Etanercept		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	106 / 127 (83.46%)		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	6 / 127 (4.72%)		
occurrences (all)	8		
Aspartate aminotransferase increased			
subjects affected / exposed	6 / 127 (4.72%)		
occurrences (all)	6		
Hepatic enzyme increased			
subjects affected / exposed	5 / 127 (3.94%)		
occurrences (all)	5		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	4 / 127 (3.15%)		
occurrences (all)	4		
Nervous system disorders			
Headache			
subjects affected / exposed	17 / 127 (13.39%)		
occurrences (all)	23		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 127 (3.15%)		
occurrences (all)	4		
Leukopenia			
subjects affected / exposed	7 / 127 (5.51%)		
occurrences (all)	8		
Neutropenia			
subjects affected / exposed	4 / 127 (3.15%)		
occurrences (all)	4		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	9 / 127 (7.09%)		
occurrences (all)	12		
Influenza like illness			

subjects affected / exposed occurrences (all)	11 / 127 (8.66%) 14		
Eye disorders Conjunctivitis subjects affected / exposed occurrences (all)	5 / 127 (3.94%) 7		
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Gastritis subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	6 / 127 (4.72%) 6 10 / 127 (7.87%) 12 5 / 127 (3.94%) 5 5 / 127 (3.94%) 5 5 / 127 (3.94%) 7		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Epistaxis subjects affected / exposed occurrences (all) Rhinitis allergic subjects affected / exposed occurrences (all)	7 / 127 (5.51%) 7 4 / 127 (3.15%) 5 4 / 127 (3.15%) 4		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	6 / 127 (4.72%) 10		

Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	13 / 127 (10.24%) 19		
Gastroenteritis subjects affected / exposed occurrences (all)	18 / 127 (14.17%) 21		
Nasopharyngitis subjects affected / exposed occurrences (all)	16 / 127 (12.60%) 19		
Pharyngitis subjects affected / exposed occurrences (all)	32 / 127 (25.20%) 50		
Rhinitis subjects affected / exposed occurrences (all)	11 / 127 (8.66%) 17		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	42 / 127 (33.07%) 84		
Ear infection subjects affected / exposed occurrences (all)	9 / 127 (7.09%) 12		
Sinusitis subjects affected / exposed occurrences (all)	6 / 127 (4.72%) 6		
Tonsillitis subjects affected / exposed occurrences (all)	9 / 127 (7.09%) 11		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 November 2009	1.AEs and SAEs were collected until 30 days after the last dose of investigational product for subjects who completed the Week 96 visit and did not consent to participate in the long-term extension study.
05 May 2011	1. AEs included progression/worsening of underlying disease. 2. AEs included signs or symptoms resulting from medication errors. 3. Lack of efficacy was reported as an AE when it has been associated with a SAE. 4. Added reporting requirements for Potential Cases of Drug-Induced Liver Injury. 5. Testing for direct and indirect bilirubin added to routine serum chemistry panel. 6. Testing for evaluation of potential Hy's Law cases added.
02 July 2012	1. Revised to indicate that the potential exists for a requirement for follow-up of AEs regardless of the investigator's assessment of causality. 2. Added that any non-serious AE that was determined by the Sponsor to be serious has been reported by the Sponsor as an SAE and that to assist in the determination of case seriousness further information may be requested from the investigator. 3. Revised the active reporting period for SAEs and added the necessity to report all SAEs after the active reporting period regardless of causality. In addition, language regarding the active reporting period and the reporting period for all AEs was revised for clarification.

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.

Results include data for Part 1 (up to Week 12) and Part 2 (up to week 96) of the study.

Notes: