



Clinical trial results:

A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Ustekinumab in the Treatment of Anti-TNF Naïve Subjects With Active Radiographic Axial Spondyloarthritis

Summary

EudraCT number	2014-003679-48
Trial protocol	CZ PL
Global end of trial date	06 September 2017

Results information

Result version number	v1 (current)
This version publication date	22 September 2018
First version publication date	22 September 2018

Trial information

Trial identification

Sponsor protocol code	CNT01275AKS3001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02437162
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen-Cilag International N.V
Sponsor organisation address	Archimedesweg 29, Leiden, Netherlands, 2333 CM
Public contact	Clinical Registry group, Janssen-Cilag International N.V, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry group, Janssen-Cilag International N.V, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 September 2017
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	06 September 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study was to assess the efficacy of ustekinumab in adult subjects with active radiographic axial spondyloarthritis (AxSpA) who were naive to anti-tumor necrosis factor alpha (TNFα) agents, as measured by the reduction in signs and symptoms of radiographic AxSpA.

Protection of trial subjects:

Safety was evaluated based on adverse events (AEs), clinical laboratory tests, vital sign measurements, physical examinations, electrocardiograms (screening only), concomitant medication review, injection-site reactions, allergic reactions, infections, and tuberculosis (TB) evaluations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 October 2015
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	Czech Republic: 33
Country: Number of subjects enrolled	Korea, Republic of: 29
Country: Number of subjects enrolled	Poland: 50
Country: Number of subjects enrolled	Russian Federation: 101
Country: Number of subjects enrolled	Taiwan: 67
Country: Number of subjects enrolled	Ukraine: 61
Country: Number of subjects enrolled	United States: 5
Worldwide total number of subjects	346
EEA total number of subjects	83

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	341
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 347 subjects were randomized and 346 subjects were treated (116 subjects to placebo, 116 subjects to ustekinumab 45 mg, and 114 subjects to 90 mg).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received placebo subcutaneous (SC) injection at Weeks 0, 4, and 16. At Week 16, subjects who met EE criteria (less than [$<$] 10 percent [%] improvement from baseline in both total back pain and morning stiffness measures at both Week 12 and Week 16) were administered open-label golimumab 50 milligram (mg) SC administrations at Week 16 and every 4 weeks (q4w) thereafter through Week 52. At Week 24 all subjects (with the exception of subjects who qualified for early escape [EE]) were re-randomized to receive either ustekinumab 45 or 90 milligram (mg) SC injection at Weeks 24 and 28 followed by every 12 weeks (q12w) dosing through Week 100.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received placebo subcutaneous (SC) injection.

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

Dosage and administration details:

Subjects who met early escape (EE) criteria were administered open-label golimumab 50 mg SC administrations at Week 16 and every 4 weeks (q4w) thereafter through Week 52.

Investigational medicinal product name	Ustekinumab 45 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects (with the exception of subjects who qualified for EE) were re-randomized to receive ustekinumab 45 mg SC injection at Weeks 24 and 28 followed by q12w dosing.

Investigational medicinal product name	Ustekinumab 90 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects (with the exception of subjects who qualified for EE) were re-randomized to receive ustekinumab 90 mg SC injection at Weeks 24 and 28 followed by every 12 weeks (q12w) dosing.

Arm title	Ustekinumab 45mg
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Arm description:

Subjects received ustekinumab 45 mg SC injection at Weeks 0 and 4, followed by every 12 week dosing, with the last administration of study agent at Week 100. At Week 16, subjects who met EE criteria were administered open-label golimumab 50 mg SC administrations at Week 16 and q4w thereafter through Week 52. At Week 24, subjects received placebo SC injection to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received ustekinumab 45 mg SC injection at Weeks 0 and 4, followed by every 12 week dosing.

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

Dosage and administration details:

Subjects who met EE criteria were administered with golimumab 50 mg SC administrations at Week 16 and q4w thereafter through Week 52.

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

Dosage and administration details:

Subjects received placebo SC injection to maintain the blind at Week 24.

Arm title	Ustekinumab 90mg
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Arm description:

Subjects received ustekinumab 90 mg SC injection at Weeks 0 and 4, followed by q12w dosing, with the last administration of study agent at Week 100. At Week 16, subjects who meet EE criteria were administered open-label golimumab 50 mg SC administrations at Week 16 and q4w thereafter through Week 52. At Week 24, subjects received placebo SC injection to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received ustekinumab 90 mg SC injection at Weeks 0 and 4, followed by q12w dosing.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use
Dosage and administration details:	
Subjects received placebo SC injection to maintain the blind at Week 24.	
Investigational medicinal product name	Golimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects who met EE criteria were administered with golimumab 50 mg SC administrations at Week 16 and q4w thereafter through Week 52.

Number of subjects in period 1	Placebo	Ustekinumab 45mg	Ustekinumab 90mg
Started	116	116	114
Early escape at Week 16	26	21	14
Cross over at week 24	87	0 ^[1]	0 ^[2]
Completed	9	8	6
Not completed	107	108	108
Study discontinued by Sponsor	93	98	97
Consent withdrawn by subject	13	7	9
Adverse event, non-fatal	-	1	-
Death	-	1	-
Unspecified	-	-	1
Lost to follow-up	1	-	1
Protocol deviation	-	1	-

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Subjects who did not met EE criteria at Week 16 were crossed over to Ustekinumab 45 or 90 mg at Week 24.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Subjects who did not met EE criteria at Week 16 were crossed over to Ustekinumab 45 or 90 mg at Week 24.

Baseline characteristics

Reporting groups

Reporting group title	Placebo
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Reporting group description:

Subjects received placebo subcutaneous (SC) injection at Weeks 0, 4, and 16. At Week 16, subjects who met EE criteria (less than [$<$] 10 percent [%] improvement from baseline in both total back pain and morning stiffness measures at both Week 12 and Week 16) were administered open-label golimumab 50 milligram (mg) SC administrations at Week 16 and every 4 weeks (q4w) thereafter through Week 52. At Week 24 all subjects (with the exception of subjects who qualified for early escape [EE]) were re-randomized to receive either ustekinumab 45 or 90 milligram (mg) SC injection at Weeks 24 and 28 followed by every 12 weeks (q12w) dosing through Week 100.

Reporting group title	Ustekinumab 45mg
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Reporting group description:

Subjects received ustekinumab 45 mg SC injection at Weeks 0 and 4, followed by every 12 week dosing, with the last administration of study agent at Week 100. At Week 16, subjects who met EE criteria were administered open-label golimumab 50 mg SC administrations at Week 16 and q4w thereafter through Week 52. At Week 24, subjects received placebo SC injection to maintain the blind.

Reporting group title	Ustekinumab 90mg
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Reporting group description:

Subjects received ustekinumab 90 mg SC injection at Weeks 0 and 4, followed by q12w dosing, with the last administration of study agent at Week 100. At Week 16, subjects who meet EE criteria were administered open-label golimumab 50 mg SC administrations at Week 16 and q4w thereafter through Week 52. At Week 24, subjects received placebo SC injection to maintain the blind.

Reporting group values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg
Number of subjects	116	116	114
Title for AgeCategorical Units: subjects			
<65	115	115	111
>=65	1	1	3
Title for AgeContinuous Units: years			
arithmetic mean	38.3	39.2	39.5
standard deviation	± 11.35	± 10.5	± 11.32
Title for Gender Units: subjects			
Female	15	23	14
Male	101	93	100

Reporting group values	Total		
Number of subjects	346		
Title for AgeCategorical Units: subjects			
<65	341		
>=65	5		
Title for AgeContinuous Units: years			
arithmetic mean	-		
standard deviation	-		

Title for Gender			
Units: subjects			
Female	52		
Male	294		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received placebo subcutaneous (SC) injection at Weeks 0, 4, and 16. At Week 16, subjects who met EE criteria (less than [$<$] 10 percent [%] improvement from baseline in both total back pain and morning stiffness measures at both Week 12 and Week 16) were administered open-label golimumab 50 milligram (mg) SC administrations at Week 16 and every 4 weeks (q4w) thereafter through Week 52. At Week 24 all subjects (with the exception of subjects who qualified for early escape [EE]) were re-randomized to receive either ustekinumab 45 or 90 milligram (mg) SC injection at Weeks 24 and 28 followed by every 12 weeks (q12w) dosing through Week 100.	
Reporting group title	Ustekinumab 45mg
Reporting group description: Subjects received ustekinumab 45 mg SC injection at Weeks 0 and 4, followed by every 12 week dosing, with the last administration of study agent at Week 100. At Week 16, subjects who met EE criteria were administered open-label golimumab 50 mg SC administrations at Week 16 and q4w thereafter through Week 52. At Week 24, subjects received placebo SC injection to maintain the blind.	
Reporting group title	Ustekinumab 90mg
Reporting group description: Subjects received ustekinumab 90 mg SC injection at Weeks 0 and 4, followed by q12w dosing, with the last administration of study agent at Week 100. At Week 16, subjects who meet EE criteria were administered open-label golimumab 50 mg SC administrations at Week 16 and q4w thereafter through Week 52. At Week 24, subjects received placebo SC injection to maintain the blind.	

Primary: Percentage of Subjects Who Achieved an Assessment of Spondyloarthritis international Society (ASAS) 40 Response at Week 24

End point title	Percentage of Subjects Who Achieved an Assessment of Spondyloarthritis international Society (ASAS) 40 Response at Week 24
End point description: ASAS 40 is defined as improvement from baseline of ≥ 40 percent (%) and with an absolute improvement from baseline of at least 2 on a 0 to 10 cm scale in at least 3 of the following 4 domains: Patient's global assessment (0 to 10 cm; 0=very well, 10=very poor), Total back pain (0 to 10 cm; 0=no pain, 10=most severe pain), BASFI (self-assessment represented as mean (0 to 10 cm; 0=easy to 10=impossible) of 10 questions, 8 of which relate to participant's functional anatomy and 2 of which relate to a participant's ability to cope with life), Inflammation (0 to 10 cm; 0=none, 10=very severe); and absence of deterioration (no worsening at all from baseline in the remaining domain) from baseline in the potential remaining domain. FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they assigned to regardless of treatment received.	
End point type	Primary
End point timeframe: Week 24	

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Percentage of subjects				
number (not applicable)	28.4	31.0	28.1	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Ustekinumab 45mg
Number of subjects included in analysis	232
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.669
Method	Cochran-Mantel-Haenszel
Parameter estimate	Percentage difference
Point estimate	2.586
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.138
upper limit	14.31

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v Ustekinumab 90mg
Number of subjects included in analysis	230
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.913
Method	Cochran-Mantel-Haenszel
Parameter estimate	Percentage difference
Point estimate	-0.646
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.18
upper limit	10.887

Secondary: Percentage of Subjects Who Achieved an ASAS 20 Response at Week 24

End point title	Percentage of Subjects Who Achieved an ASAS 20 Response at Week 24
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End point description:

ASAS 20 is an improvement from baseline of $\geq 20\%$ and with an absolute improvement from baseline of at least 1 on a 0 to 10 scale in at least 3 of the following 4 domains: Patient global; Total back pain; BASFI (0 to 10 cm; 0=easy to 10=impossible) of 10 questions, 8 of which relate to participant's functional anatomy and 2 relate to participant's ability to cope with everyday life); Inflammation (0 to 10 cm; 0=none, 10=very severe) and absence of deterioration from baseline ($\geq 20\%$ and worsening of at least 1 on a 0 to 10 scale) in the potential remaining domain. ASAS20 response based on imputed

data using treatment failure(consider non-responders at and after treatment failure),early escape rules(consider non-responder at Week 20 and 24),non-responder[NRI] (missing responses at post baseline visit imputed as non-responder). FAS population was included. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received.

End point type	Secondary
End point timeframe:	
Week 24	

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Percentage of subjects				
number (not applicable)	44.8	55.2	50.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved at Least a 50 Percent (%) Improvement From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) at Week 24

End point title	Percentage of Subjects who Achieved at Least a 50 Percent (%) Improvement From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) at Week 24
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End point description:

BASDAI used to measure AS disease severity,consists of 6 questions:fatigue,spinal pain,arthralgia,enthesitis (inflammation of tendons and ligaments),morning stiffness(2questions:duration and severity). Each question to answer 10 cm visual analog scale(VAS),0(none),10(very severe) and for the last question related to morning stiffness duration: 0(0 hours), 10(2 or more hours).Final BASDAI score (ranging 0-10) is average of overall total score. Higher BASDAI score indicates more severe AS symptom. Missing data is imputed using treatment failure(consider non-responders at and after treatment failure),early escape rules(consider non-responder at Week 20 and 24),non-responder[NRI](missing responses at post baseline visit imputed as non-responder). FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they were

End point type	Secondary
End point timeframe:	
Week 24	

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Percentage of subejcts				
number (not applicable)	27.6	25.0	25.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI) Total Score at Week 24

End point title	Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI) Total Score at Week 24
End point description: BASFI composed 10 questions (each question answered with VAS (0-10 cm) to assess disease severity, including first 8 questions regarding to functional anatomy related activities and remaining 2 questions related to daily activities of AS subjects. Each question is 10cm VAS with value 0(easy), 10(impossible). Final BASFI score mean of 10 scores. BASFI score is average of 10 responses, has minimum value of 0, maximum value 10. Higher BASFI score indicates more severe functional limitations of subject due to AS. Early escape rule was applied (measurement value at Wk20 and Wk 24 was set as missing). FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group were assigned regardless of treatment received. Here 'N' (number of participants analyzed) signifies number of participants who were evaluable for this endpoint.	
End point type	Secondary
End point timeframe: Baseline and Week 24	

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	88	95	99	
Units: Units on a scale				
arithmetic mean (standard deviation)	-1.85 (± 2.133)	-2.11 (± 2.266)	-2.07 (± 2.502)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved Ankylosing Spondylitis Disease Activity Score-C Reactive Protein (ASDAS-CRP) Inactive Disease (<1.3) at Week 24

End point title	Percentage of Subjects who Achieved Ankylosing Spondylitis Disease Activity Score-C Reactive Protein (ASDAS-CRP) Inactive Disease (<1.3) at Week 24
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End point description:

ASDAS includes CRP milligram per liter(mg/L); four additional self-reported items (rated on 0-10cm VAS or 0-10 NRS) included total back pain (TBP), duration of morning stiffness (DMS), peripheral pain(PP)/swelling and patient global assessment(PGA). ASDAS calculated as: $ASDAS(CRP) = (0.121 * TBP) + (0.110 * PG) + (0.073 * PP/swelling) + (0.058 * DMS) + (0.579 * \ln(CRP + 1))$,

(0 [normal] to 10 [very severe]), DMS on NRS (0 to 10, 0 none, 10 representing duration => 2 hours). Inactive disease (ID) defined as ASDAS score < 1.3. ASDAS (CRP) ID is based on imputed data using treatment failure (consider non-responders at and after treatment failure), early escape rules (consider non-responder at Week 20 and 24), NRI (missing responses at post baseline visit imputed as non-responder). FAS included subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they assigned regardless treatment received.

End point type	Secondary
End point timeframe:	
Week 24	

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Percentage of subjects				
number (not applicable)	3.4	1.7	2.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in hsCRP Through Week 24

End point title	Change From Baseline in hsCRP Through Week 24
End point description:	
Change from baseline in hsCRP levels were reported. hsCRP is a sensitive laboratory assay for serum levels of C-Reactive Protein, which is a biomarker of inflammation. Early escape rule was applied (measurement value at Week 20 and Week 24 was set as missing). FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received. Here 'n' signifies number of subjects who were analyzed at each specified timepoint, for each arm, respectively.	
End point type	Secondary
End point timeframe:	
Baseline, Week 4, 8, 12, 16, 20 and 24	

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Milligrams per decilitre (mg/dL)				
arithmetic mean (standard deviation)				
Week 4 (n=115,116,113)	-0.10 (± 1.459)	-0.54 (± 1.488)	-0.74 (± 1.839)	
Week 8 (n=116,115,114)	-0.16 (± 1.478)	-0.59 (± 1.236)	-0.66 (± 2.213)	
Week 12 (n=115,115,112)	-0.18 (± 1.571)	-0.80 (± 1.853)	-0.84 (± 2.262)	

Week 16 (n=115,116,114)	-0.11 (± 1.456)	-0.39 (± 3.166)	-0.86 (± 2.261)	
Week 20 (n=88,93,99)	-0.34 (± 1.450)	-0.73 (± 1.792)	-0.79 (± 2.240)	
Week 24 (n=87,95,98)	-0.41 (± 1.737)	-0.72 (± 1.617)	-0.92 (± 2.274)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) at Week 16 and 24

End point title	Change From Baseline in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) at Week 16 and 24
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End point description:

Assessment of enthesitis was performed in the following 7 domains: 1) 1st costochondral joint left and right, 2) 7th costochondral joint left and right, 3) posterior superior iliac spine left and right, 4) anterior superior iliac spine left and right, 5) iliac crest left and right, 6) 5th lumbar spinous process and 7) proximal insertion of Achilles tendon left and right. Entheses were scored as either 0 (nontender) or 1 (tender) yielding total MASES ranging from 0 (no tenderness) to 13 (worst possible score; severe tenderness). Early escape rule was applied (measurement value at Wk 20 and Wk 24 was set as missing). Population included subset of FAS with enthesitis at baseline. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received. Here 'n' signifies number of subjects who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline, Week 16 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	87	92	83	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Week 16 (n=62,59,58)	-1.53 (± 3.347)	-1.47 (± 3.564)	-1.17 (± 3.101)	
Week 24 (n=35,38,44)	-1.66 (± 3.481)	-1.84 (± 3.301)	-1.73 (± 3.060)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Bath Ankylosing Spondylitis Metrology Index (BASMI) at Week 16 and 24

End point title	Change From Baseline in Bath Ankylosing Spondylitis Metrology Index (BASMI) at Week 16 and 24
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End point description:

The Bath Ankylosing Spondylitis Metrology Index linear function is a combined index of 5 clinical measurements (performed by the Joint Assessor) which reflect axial mobility in the AS patient. The measurements to assess mobility are: 1)Tragus-to-wall; 2)Modified Schober (lumbar flexion); 3)Cervical rotation angle; 4)Lateral spinal flexion; 5)Intermalleolar distance. The BASMI linear result is the average of the 5 assessments and ranges from 0 to 10. The higher the BASMI score the more severe the patient's limitation of movement due to their AS. Early escape rule was applied (measurement value was set as missing).FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received. 'n' signifies number of subjects who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline, Week 16 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Week 16 (n=114,114,111)	-0.26 (± 1.015)	-0.26 (± 1.044)	-0.17 (± 0.840)	
Week 24 (n=87,92,97)	-0.36 (± 0.943)	-0.37 (± 0.946)	-0.27 (± 0.877)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Ankylosing Spondylitis Quality of Life questionnaire (ASQoL) Score at Week 16 and 24

End point title	Change from Baseline in Ankylosing Spondylitis Quality of Life questionnaire (ASQoL) Score at Week 16 and 24
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End point description:

The ASQoL is a self-administered health-related quality of life (HRQOL) instrument. It consists of 18 items requesting a Yes or No response to questions related to the impact of the disease/condition (including pain) on sleep, mood, motivation, ability to cope, activities of daily living, independence, relationships, and social life. A score of 1 is given to a response of "yes" on each item and all item scores are summed to a total score with a range of 0 to 18. Higher scores indicate worse HRQOL. Early Escape rule was applied (measurement value was set as missing). FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received. Here 'n' signifies number of subjects who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline, Week 16 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Week 16 (n=114,116,113)	-2.61 (± 4.385)	-3.03 (± 4.416)	-2.93 (± 3.954)	
Week 24 (n=87,94,98)	-4.21 (± 4.441)	-4.48 (± 4.808)	-4.31 (± 4.537)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Score at Week 16 and 24

End point title	Change From Baseline in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Score at Week 16 and 24
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End point description:

FACIT-Fatigue score calculated according to 13-item questionnaire that assesses self-reported fatigue and its impact upon daily activities and function. Subjects scored each item on 5-point scale:0 (Not at all) to 4(Very much). Larger participant's response to questions (exception of 2 negatively stated), greater participant's fatigue. All questions, except for 2 negatively stated ones, code was reversed, new score was calculated(4 minus participant's response). Sum of all responses resulted in FACIT-Fatigue score for total possible score of 0 (worst score) to 52 (best score). Early escape rule was applied (measurement value was set as missing).FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received. 'n' signifies number of subjects who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline, Week 16 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Week 16 (n=114,116,113)	5.71 (± 9.499)	5.44 (± 9.528)	5.96 (± 9.325)	
Week 24 (n=87,94,98)	8.78 (± 10.472)	7.67 (± 10.348)	8.59 (± 10.597)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Norm-Based SF-36 Physical Component Summary (PCS) and SF-36 Mental Component Summary (MCS) at Week 16 and 24

End point title	Change From Baseline in Norm-Based SF-36 Physical Component Summary (PCS) and SF-36 Mental Component Summary (MCS) at Week 16 and 24
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End point description:

Medical Outcome Study health measure SF-36 questionnaire is well-validated and widely used quality-of-life instrument. It is self-administered survey consists of 8 multi-item scales: The 4 subscales of SF-36 comprises the PCS(physical functioning, role-physical, bodily pain, and general health), 4 subscales of SF-36, MCS score(vitality, social functioning, role-emotional,mental health). PCS and MCS scored from 0 to 100 with higher scores means better health (worst value is 0 and best value is 100), which are scored using norm-based system. Early escape rule was applied (measurement value at W20 and 24 was set as missing). FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received. Here 'n' signifies number of subjects who were analyzed at each specified timepoint, for each arm.

End point type	Secondary
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End point timeframe:

Baseline, Week 16 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Units on a scale				
arithmetic mean (standard deviation)				
SF-36 PCS; change at Wk16 (n=114,116,114)	4.09 (± 7.618)	3.66 (± 6.172)	5.17 (± 6.494)	
SF-36 PCS; change at Wk 24 (n=87,94,98)	7.69 (± 8.001)	6.34 (± 6.198)	7.20 (± 7.343)	
SF-36 MCS; change at Wk16 (n=114,116,114)	4.56 (± 9.113)	3.69 (± 9.690)	4.06 (± 9.034)	
SF-36 MCS; change at Wk 24 (n=87,94,98)	5.05 (± 9.758)	4.82 (± 10.841)	5.46 (± 8.911)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in BASDAI Inflammation Score Through Week 24

End point title	Change From Baseline in BASDAI Inflammation Score Through Week 24
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End point description:

The BASDAI is used to measure the ankylosing spondylitis (AS) disease severity. It consists of 6 questions: fatigue, spinal pain, arthralgia (joint pain) or swelling, enthesitis (inflammation of tendons and ligaments), and morning stiffness. Each question is an easy to answer 10 centimeter (cm) visual analog scale (VAS), with 0 being none, and 10 being very severe and the last question: 0=0 hours, 10=2 or more hours. Change from baseline in inflammation was assessed by calculating the average of the Last 2 Questions of the BASDAI Concerning Morning Stiffness. Early escape rule was applied (measurement value was set as missing). FAS included subjects who were randomized and received at least one administration of study agent and analyzed based on randomized treatment group assigned regardless treatment received. 'n' signifies number of participants analyzed for this endpoint at specific timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Week 4, 8, 12, 16, 20 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Week 4 (n=116,116,114)	-0.86 (± 1.650)	-1.09 (± 1.748)	-1.25 (± 1.871)	
Week 8 (n=116,115,114)	-1.45 (± 1.970)	-1.80 (± 2.192)	-1.88 (± 2.160)	
Week 12 (n=116,115,112)	-1.63 (± 2.110)	-1.89 (± 2.143)	-1.88 (± 2.110)	
Week 16 (n=115,116,114)	-1.82 (± 2.221)	-1.98 (± 2.394)	-1.97 (± 2.299)	
Week 20 (n=86,92,98)	-2.48 (± 2.200)	-2.61 (± 2.089)	-2.51 (± 2.429)	
Week 24 (n=88,95,99)	-2.64 (± 2.194)	-2.81 (± 2.257)	-2.74 (± 2.592)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Composite and Domain Scores of Medical Outcomes Study Sleep Scale (MOS-SS) at Week 16 and 24

End point title	Change From Baseline in Composite and Domain Scores of Medical Outcomes Study Sleep Scale (MOS-SS) at Week 16 and 24
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End point description:

Sleep problems (SP) assessed using the 12-item MOS-SS, a generic instrument designed to assess 6 dimensions of sleep: Sleep disturbance(SD), Somnolence, Sleep adequacy (SA), Snoring, Awaken short of breath (ASB) or headache, Quantity of sleep(QS)/optimal sleep(OS) during past 4W. 6 dimensions used to generate composite Sleep Problems Index (SPI). Increase in score from baseline represents improvement. SD, snoring, somnolence, ASB, SP index have score ranges 0(no SP) to 100 (greater SP), negative change indicates improvement. SA scored 0 (least SA) to 100 (better SA), positive change indicates improvement. QS is scored 0 (less QS) to 24 (greater QS), positive change indicates improvement. EE rule was applied (measurement value was set as missing). FAS included subjects randomized, received at least one administration of study agent and analyzed as per treatment group assigned regardless treatment received. 'n': number of subjects analyzed for this endpoint at specific timepoint.

End point type	Secondary
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End point timeframe:

Baseline, Week 16 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Units on a scale				
arithmetic mean (standard deviation)				
W16: sleep disturbance (n=114,116,113)	3.15 (± 7.103)	4.13 (± 7.815)	2.79 (± 6.233)	
W24: sleep disturbance (n=88,94,98)	4.57 (± 7.335)	5.85 (± 8.991)	4.79 (± 7.232)	
W16: somnolence (n=114,116,113)	3.79 (± 7.996)	2.06 (± 7.901)	2.73 (± 8.525)	
W24: somnolence (n=88,94,98)	4.99 (± 8.019)	3.16 (± 8.612)	4.52 (± 9.131)	
W16: sleep adequacy (n=114,116,113)	1.78 (± 7.713)	1.42 (± 9.301)	1.50 (± 7.851)	
W24: sleep adequacy (n=88,94,98)	3.03 (± 7.245)	1.75 (± 9.148)	3.41 (± 7.689)	
W16: snoring (n=114,116,113)	0.47 (± 7.026)	1.24 (± 5.753)	1.14 (± 6.520)	
W24: snoring (n=88,94,98)	0.86 (± 7.506)	1.21 (± 6.715)	2.64 (± 7.569)	
W16:awaken short of breath/headache(n=114,116,113)	3.93 (± 12.209)	3.66 (± 11.355)	5.53 (± 12.602)	
W24:awaken short of breath/headache (n=88,94,98)	3.48 (± 11.179)	2.76 (± 11.385)	3.97 (± 12.426)	
W16: sleep problems index(n=114,116,113)	3.72 (± 7.341)	3.76 (± 8.160)	3.19 (± 6.695)	
W24:sleep problems index(n=88,94,98)	5.10 (± 7.338)	4.96 (± 8.794)	5.16 (± 7.795)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Composite and Domain Scores of Medical Outcomes Study Sleep Scale (MOS-SS)-Quantity of Sleep/Optimal Sleep at Week 16 and 24

End point title	Change From Baseline in Composite and Domain Scores of Medical Outcomes Study Sleep Scale (MOS-SS)-Quantity of Sleep/Optimal Sleep at Week 16 and 24
End point description:	
Sleep problems were assessed using the 12-item MOS-SS, a generic instrument designed to assess 6 dimensions of sleep: Sleep disturbance, Somnolence, SA, Snoring, Awaken short of breath or headache, QS/OS during past W4. 6 dimensions used to generate composite SPI. SA scored 0 (least SA) to 100 (better SA), positive change mean improvement. QS is scored 0 (less QS) to 24 (greater QS), positive change mean improvement. Single-item QS asks subjects to estimate average number of hours they slept each night during past 4W (0-24h) and transformed into dichotomous OS Score, reported 7 or 8h of sleep considered Optimal. OS is Yes if average hour of sleep is in range of 7-8h. Early escape rule was applied(measurement value was set as missing).FAS: subjects who were randomized, received at least one administration of study agent, analyzed as per treatment group assigned regardless treatment received. 'n': number of subjects analyzed for this endpoint at specific timepoint.	
End point type	Secondary
End point timeframe:	
Baseline, Week (W) 16 and 24	

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Hours				
arithmetic mean (standard deviation)				
Change-W16: QS/OS(n=114,116,113)	0.15 (± 0.502)	0.06 (± 0.548)	0.04 (± 0.557)	
Change-W24: QS/OS(n=88,94,98)	0.16 (± 0.500)	0.07 (± 0.626)	0.12 (± 0.579)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With at Least a 40% Improvement From Baseline in ASAS 40 Components at Week 24

End point title	Percentage of Subjects With at Least a 40% Improvement From Baseline in ASAS 40 Components at Week 24
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End point description:

ASAS 40 components included Patient's global assessment (0 to 10cm; 0=very well,10=very poor),total back pain (0 to 10cm; 0=no pain,10=most severe pain), BASFI (self-assessment represented as mean (0 to 10 cm; 0=easy to 10=impossible) of 10 questions, 8 of relate to participant's functional anatomy and 2 relate to participant's ability to cope with everyday life), Inflammation (0 to 10cm;0=none,10=very severe). Percentage of Participants With at least a 40% improvement from baseline in each of the ASAS components was calculated. FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received. Here 'n' signifies number of participants who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
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End point timeframe:

Week 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Percentage of subjects				
number (not applicable)				
Patients global assessment (n=114,115,113)	43.0	35.7	31.9	
Total back pain (n=114,115,113)	42.1	42.6	38.9	
Function (n=114,115,113)	32.5	33.0	35.4	
Inflammation (n=114,115,113)	47.4	36.5	37.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved at Least 50%, 20%, 70% and 90% Improvement From Baseline in BASDAI Through Week 24

End point title	Percentage of Subjects who Achieved at Least 50%, 20%, 70% and 90% Improvement From Baseline in BASDAI Through Week 24
End point description:	
BASDAI used to measure the AS disease severity. It consists of 6 questions: fatigue, spinal pain, arthralgia (joint pain) or swelling, enthesitis (inflammation of tendons and ligaments), and morning stiffness (2 questions: duration and severity. Higher BASDAI score indicates more severe AS symptom. 20 %,50%, 70%,90% improvement in BASDAI based on imputed data using treatment failure(consider non-responders at and after treatment failure),early escape rules(consider non-responder at Week 20 and 24), NRI(missing responses at post baseline visit imputed as non-responders). FAS included subjects who were randomized and received at least one administration of study agent and analyzed based on randomized treatment group assigned regardless treatment received.	
End point type	Secondary
End point timeframe:	
Baseline, Week 4, 8, 12, 16, 20 and 24	

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Percentage of subjects				
number (not applicable)				
Week 4 (20% improvement)	25.9	28.4	35.1	
Week 8 (20% improvement)	44.8	45.7	43.0	
Week 12 (20% improvement)	47.4	45.7	41.2	
Week 16 (20% improvement)	49.1	46.6	48.2	
Week 20 (20% improvement)	43.1	51.7	50.0	
Week 24 (20% improvement)	47.4	55.2	51.8	
Week 4 (50% improvement)	3.4	4.3	5.3	
Week 8 (50% improvement)	12.9	12.9	14.0	
Week 12 (50% improvement)	19.0	12.9	14.0	
Week 16 (50% improvement)	19.8	17.2	18.4	
Week 20 (50% improvement)	25.9	17.2	22.8	
Week 4 (70% improvement)	0.9	0.9	1.8	
Week 8 (70% improvement)	6.9	4.3	5.3	
Week 12 (70% improvement)	6.9	6.9	7.9	
Week 16 (70% improvement)	10.3	9.5	8.8	
Week 20 (70% improvement)	11.2	6.9	10.5	
Week 24 (70% improvement)	11.2	11.2	11.4	
Week 4 (90% improvement)	0	0.9	0	
Week 8 (90% improvement)	0.9	0	1.8	
Week 12 (90% improvement)	1.7	0.9	1.8	
Week 16 (90% improvement)	1.7	1.7	0.9	
Week 20 (90% improvement)	2.6	0.9	1.8	
Week 24 (90% improvement)	4.3	1.7	4.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in BASDAI Total Score Through Week 24

End point title	Change From Baseline in BASDAI Total Score Through Week 24
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End point description:

BASDAI used to measure the AS disease severity. It consists of 6 questions: fatigue, spinal pain, arthralgia (joint pain) or swelling, enthesitis (inflammation of tendons and ligaments), and morning stiffness (2 questions: duration and severity). Each question is easy to answer 10 cm VAS, 0 being none, 10 being very severe and the last question is: 0=0 hours, 10=2 or more hours. Order to give each of 5 symptoms equal weight, mean of 2 questions about morning stiffness added to total of remaining 4 scores, final BASDAI score (ranging 0-10) is the average of the overall total score. Higher BASDAI score indicates more severe AS symptom. Early escape rule was applied (measurement value at Week 20 and Week 24 was set as missing). FAS population was included and analyzed based on randomized treatment group assigned regardless treatment received. Here 'n' signifies number of participants who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline, Week 4, 8, 12, 16, 20 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Week 4 (116,116,114)	-0.83 (± 1.340)	-0.92 (± 1.550)	-0.87 (± 1.632)	
Week 8 (n=116,115,114)	-1.43 (± 1.849)	-1.67 (± 1.984)	-1.49 (± 2.025)	
Week 12 (n=116,115,112)	-1.59 (± 2.073)	-1.64 (± 2.047)	-1.45 (± 2.118)	
Week 16 (n=115,116,114)	-1.67 (± 2.271)	-1.74 (± 2.300)	-1.60 (± 2.276)	
Week 20 (n=86,92,98)	-2.35 (± 2.226)	-2.39 (± 1.922)	-2.20 (± 2.283)	
Week 24 (n=88,95,99)	-2.52 (± 2.262)	-2.56 (± 2.196)	-2.40 (± 2.356)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved ASAS 40 Response at Week 4, 8, 12, 16 and 20

End point title	Percentage of Subjects Who Achieved ASAS 40 Response at Week 4, 8, 12, 16 and 20
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End point description:

ASAS 40 defined as improvement from baseline of $\geq 40\%$ and with an absolute improvement from baseline of at least 2 on 0 to 10cm scale in at least 3 of following 4 domains: PGA of disease activity (0 to 10cm; 0=very well, 10=very poor), TBP (0 to 10cm; 0=no pain, 10=most severe pain), BASFI (self-assessment represented as mean (0 to 10 cm; 0=easy to 10=impossible) of 10 questions, 8 of relate to

subject's functional anatomy, 2 relate to subject's ability to cope with life), Inflammation (0 to 10cm;0=none,10=very severe); no worsening at all from baseline in remaining domain. ASAS40 based on imputed data using treatment failure(consider non-responders at and after treatment failure),early escape rules(consider non-responder at Week 20 and 24),non-responder[NRI] (missing responses at post baseline visit imputed as non-responder).FAS population was included and analyzed based on randomized treatment group assigned regardless treatment received.

End point type	Secondary
End point timeframe:	
Week 4, 8, 12, 16, and 20	

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Percentage of subjects				
number (not applicable)				
Week 4 (ASAS 40)	7.8	6.9	8.8	
Week 8 (ASAS 40)	14.7	18.1	19.3	
Week 12 (ASAS 40)	19.8	14.7	18.4	
Week 16 (ASAS 40)	22.4	21.6	22.8	
Week 20 (ASAS 40)	22.4	22.4	28.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved ASAS 20 Response at Week 4, 8, 12, 16 and 20

End point title	Percentage of Subjects Who Achieved ASAS 20 Response at Week 4, 8, 12, 16 and 20
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End point description:

ASAS 20 defined as improvement from baseline of $\geq 20\%$ and absolute improvement of 1 on 0 to 10cm in atleast 3 of 4 domains: PGA disease activity 0 to 10cm;0=very well,10=very poor,TBP 0 to10cm; 0=no pain,10=most severe pain, BASFI(self-assessment represented as 0 to 10cm; 0=easy to10=impossible of 10 questions,8 of which relate subject's functional anatomy,2 relate to subject's ability to cope with life),Inflammation(0 to 10cm;0=none,0=very severe);absence of deterioration($\geq 20\%$,worsening of atleast 1 on 0to10cm) from baseline in remaining domain. ASAS20 based on imputed data using treatment failure(consider non-responders at and after treatment failure),early escape rules(consider non-responder at Wk 20 and 24),non-responder[NRI] (missing responses at post baseline visit imputed as non-responder).FAS population was included and analyzed based on randomized treatment group assigned regardless treatment received.

End point type	Secondary
End point timeframe:	
Week 4 , 8, 12, 16 and 20	

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Percentage of subjects				
number (not applicable)				
Week 4	20.7	27.6	29.8	
Week 8	33.6	41.4	42.1	
Week 12	37.1	44.8	39.5	
Week 16	44.0	45.7	43.9	
Week 20	39.7	46.6	49.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved Assessment of Spondyloarthritis international Society (ASAS) Partial Remission Through Week 24

End point title	Percentage of Subjects who Achieved Assessment of Spondyloarthritis international Society (ASAS) Partial Remission Through Week 24
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End point description:

Low level of disease activity was measured by criteria for ASAS partial remission, defined as a value below 2 on a scale of 0 to 10 cm in each of the 4 ASAS domains: patient's global assessment of disease activity, total back pain, function (BASFI), inflammation. ASAS partial remission response based on imputed data using treatment failure(consider non-responders at and after treatment failure),early escape rules(consider non-responder at Week 20 and 24),non-responder[NRI] (missing responses at post baseline visit imputed as non-responder). FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received.

End point type	Secondary
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End point timeframe:

Week 4, 8, 12, 16, 20 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Percentage of subjects				
number (not applicable)				
Week 4	1.7	0	0.9	
Week 8	3.4	0.9	3.5	
Week 12	4.3	4.3	3.5	
Week 16	8.6	5.2	2.6	
Week 20	7.8	3.4	6.1	
Week 24	6.9	5.2	6.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved ASAS 5/6 Response at Week 16 and 24

End point title	Percentage of Subjects Who Achieved ASAS 5/6 Response at Week 16 and 24
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End point description:

ASAS 5/6 is defined as a $\geq 20\%$ improvement in any 5 of the 6 domains of pain (VAS 0 to 10), patient global (VAS 0 to 10), function (BASFI score), morning stiffness (from BASDAI), hsCRP, and spine mobility (lumbar side flexion). ASAS 5/6 response is based on imputed data using treatment failure (consider non-responders at and after treatment failure), early escape rules (consider non-responder at Week 20 and 24), non-responder [NRI] (missing responses at post baseline visit imputed as non-responder). FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received.

End point type	Secondary
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End point timeframe:

Week 16 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Percentage of subjects				
number (not applicable)				
Week 16	23.3	29.3	26.3	
Week 24	30.2	35.3	33.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Ankylosing Spondylitis Disease Activity Score ASDAS (CRP) Through Week 24

End point title	Change From Baseline in Ankylosing Spondylitis Disease Activity Score ASDAS (CRP) Through Week 24
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End point description:

ASDAS includes CRP mg/L; 4 additional self-reported items (rated 0-10cm VAS or 0-10 numerical rating scale [NRS]) included are total back pain (TBP), duration of morning stiffness (DMS), peripheral pain/swelling and patient global assessment (PGA). ASDAS scores calculated as: $ASDAS(CRP) = (0.121 \times TBP) + (0.110 \times PGA) + (0.073 \times \text{peripheral pain}(PP)/\text{swelling}) + (0.058 \times \text{duration of morning stiffness}) + (0.579 \times \ln(CRP + 1))$. The disease activity, TBP, and PP/swelling on a NRS (0 [normal]–10 [very severe]) and DMS on NRS (0 to 10, 0 being none and 10 representing a duration ≥ 2 hrs). Missing values were imputed using early escape rule (measurement value was set as missing). FAS included subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group assigned to regardless treatment received. Here 'n' signifies number of subjects who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline, Week 4, 8, 12, 16, 20 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n=113,116,113)	-0.41 (± 0.705)	-0.52 (± 0.616)	-0.55 (± 0.673)	
Change at Week 8 (n=114,115,114)	-0.62 (± 0.881)	-0.80 (± 0.764)	-0.75 (± 0.875)	
Change at Week 12 (n=113,114,112)	-0.66 (± 0.957)	-0.87 (± 0.800)	-0.76 (± 0.881)	
Change at Week 16 (n=113,116,114)	-0.67 (± 1.044)	-0.85 (± 0.972)	-0.80 (± 0.926)	
Change at Week 20 (n=84,92,98)	-1.00 (± 1.033)	-1.13 (± 0.844)	-1.01 (± 0.982)	
Change at Week 24 (n=85,95,98)	-1.10 (± 1.088)	-1.19 (± 0.985)	-1.12 (± 1.005)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved ASDAS (CRP) Inactive Disease (<1.3) at Week 4, 8, 12, 16 and 20

End point title	Percentage of Subjects who Achieved ASDAS (CRP) Inactive Disease (<1.3) at Week 4, 8, 12, 16 and 20
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End point description:

ASDAS includes CRP mg/L; four additional self-reported items (rated on 0-10cm VAS or 0-10 NRS) included are TBP, duration of DMS, peripheral pain(PP)/swelling and PGA. ASDAS calculated: $ASDAS(CRP) = (0.121 * TBP) + (0.110 * PGA) + (0.073 * \text{peripheral pain/swelling}) + (0.058 * DMS) + (0.579 * \ln(CRP + 1))$. The disease activity, TBP, PP/swelling on NRS (0 (normal) to 10 (very severe), DMS on NRS (0 to 10, with 0 being none, 10 representing duration of $\geq 2h$). Clinically improvement in ASDAS defined as decrease from baseline ≥ 1.1 . ASDAS (CRP Inactive Disease (<1.3) based on imputed data using treatment failure (consider non-responders at and after treatment failure), early escape rules (consider non-responder at Week 20 and 24), NRI (missing responses at post baseline visit imputed as non-responders). FAS included subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group assigned to regardless treatment received.

End point type	Secondary
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End point timeframe:

Week 4, 8, 12, 16, and 20

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Percentage of subjects				
number (not applicable)				
Week 4	0.9	0	0	
Week 8	0.9	0.9	2.6	
Week 12	1.7	0.9	0.9	
Week 16	1.7	1.7	2.6	
Week 20	4.3	0.9	2.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With ASDAS (CRP) Major Improvement (Decrease ≥ 2.0) Through Week 24

End point title	Percentage of Subjects With ASDAS (CRP) Major Improvement (Decrease ≥ 2.0) Through Week 24
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End point description:

ASDAS includes CRP mg/L; four additional self-reported items (rated on 0-10cm VAS or 0-10 NRS) included are TBP, duration of DMS, peripheral pain(PP)/swelling and PGA. ASDAS calculated: $ASDAS(CRP) = (0.121 * TBP) + (0.110 * PGA) + (0.073 * \text{peripheral pain/swelling}) + (0.058 * DMS) + (0.579 * \ln(CRP + 1))$. The disease activity, TBP, PP/swelling on NRS(0 (normal) to 10 (very severe), DMS on NRS (0 to 10, with 0 being none, 10 representing duration of $\geq 2h$). Clinically improvement in ASDAS defined as decrease from baseline ≥ 1.1 . ASDAS (CRP) major important improvement (decrease ≥ 2.0) based on imputed data using treatment failure(consider non-responders at and after treatment failure), early escape rules(consider non-responder at Week 20 and 24), NRI(missing responses at post baseline visit imputed as non-responders). FAS included subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group assigned to regardless treatment received.

End point type	Secondary
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End point timeframe:

Baseline, Week 4, 8, 12, 16, 20 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Percentage of subjects				
number (not applicable)				
Week 4	2.6	3.4	3.5	
Week 8	6.9	8.6	12.3	
Week 12	8.6	9.5	12.3	
Week 16	10.3	13.8	14.0	
Week 20	7.8	15.5	10.5	
Week 24	13.8	16.4	14.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved ASDAS (CRP) Clinically Important Improvement (Decrease ≥ 1.1) Through Week 24

End point title	Percentage of Subjects who Achieved ASDAS (CRP) Clinically Important Improvement (Decrease ≥ 1.1) Through Week 24
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End point description:

ASDAS includes CRP mg/L; four additional self-reported items (rated on 0-10cm VAS or 0-10 NRS) included are TBP, duration of DMS, peripheral pain(PP)/swelling and PGA. ASDAS calculated: $ASDAS(CRP) = (0.121 * TBP) + (0.110 * PGA) + (0.073 * \text{peripheral pain/swelling}) + (0.058 * DMS) + (0.579 * \ln(CRP + 1))$. The disease activity, TBP, PP/swelling on NRS (0 (normal) to 10 (very severe)), DMS on NRS (0 to 10, with 0 being none, 10 representing duration of ≥ 2 h). Clinically improvement in ASDAS defined as decrease from baseline ≥ 1.1 . ASDAS (CRP) clinical important improvement (decrease ≥ 1.1) based on imputed data using treatment failure (consider non-responders at and after treatment failure), early escape rules (consider non-responder at Week 20 and 24), NRI (missing responses at post baseline visit imputed as non-responders). FAS included subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group assigned to regardless treatment received.

End point type	Secondary
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End point timeframe:

Baseline, Week 4, 8, 12, 16, 20 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Percentage of subjects				
number (not applicable)				
Week 4	16.4	13.8	17.5	
Week 8	26.7	31.0	30.7	
Week 12	28.4	37.9	28.1	
Week 16	32.8	35.3	28.1	
Week 20	29.3	31.9	37.7	
Week 24	37.9	40.5	37.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in BASFI Score at Week 4, 8, 12, 16 and 20

End point title	Change From Baseline in BASFI Score at Week 4, 8, 12, 16 and 20
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End point description:

The BASFI is composed with 10 questions (each question is answered with a visual analogue scale 0-10 cm) to assess the disease severity, including the first 8 questions regarding to functional anatomy related activities and the remaining 2 questions related to daily activities of AS participants. Each question is a 10cm VAS with a value between 0 (easy) and 10 (impossible). The final BASFI score is the mean of the 10 scores. The BASFI score is the average of the 10 responses and has a possible minimum value of 0 and a possible maximum value of 10. Higher BASFI score indicates more severe functional limitations of the participant due to AS. Change from baseline in BASFI score were imputed using early escape rule (measurement value at Week 20 and Week 24 was set as missing). FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received.

End point type	Secondary
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End point timeframe:

Baseline , Week 4, 8, 12, 16, and 20

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 4(n=116,116,114)	-0.77 (± 1.635)	-0.80 (± 1.359)	-0.90 (± 1.524)	
Change at Week 8(n=116,115,114)	-1.13 (± 1.841)	-1.29 (± 1.904)	-1.29 (± 1.841)	
Change at Week 12 (n=116,115,112)	-1.09 (± 2.015)	-1.22 (± 1.854)	-1.34 (± 2.001)	
Change at Week 16(n=115,116,114)	-1.08 (± 2.179)	-1.35 (± 2.113)	-1.43 (± 2.125)	
Change at Week 20 (n=86,92,98)	-1.71 (± 2.160)	-1.94 (± 1.946)	-2.01 (± 2.291)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Chest Expansion at Week 16 and 24

End point title	Change From Baseline in Chest Expansion at Week 16 and 24
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End point description:

Chest expansion is the difference, in centimeter (cm), between the circumference of the chest in maximal inspiration and maximal expiration. It is measured at the level of the fourth intercostal space in males, and just below the breasts in females. Change from baseline in chest expansion were imputed using early escape rule (measurement value at Week 20 and Week 24 was set as missing). FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received. Here 'n' signifies number of subjects who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline , Week 16 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: centimeter(cm)				
arithmetic mean (standard deviation)				
Change at Week 16 (n=114,113,111)	0.43 (± 7.899)	0.20 (± 2.209)	-0.02 (± 2.240)	
Change at Week 24(n=87,92,97)	-0.16 (± 2.370)	0.32 (± 1.939)	-0.21 (± 2.232)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total Back Pain (TBP) and Night Back Pain (NBP) Through Week 24

End point title	Change From Baseline in Total Back Pain (TBP) and Night Back Pain (NBP) Through Week 24
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End point description:

The total back pain and nighttime back pain was measured on a VAS (0 to 10 cm; 0 = no pain, 10 = most severe pain). Change from baseline in TBP and NBP were imputed using early escape rule (measurement value at Week 20 and Week 24 was set as missing). FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received. Here 'n' signifies number of subjects who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline, Week 4, 8, 12, 16, 20 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: centimeter				
arithmetic mean (standard deviation)				
Change -W4 in TBP (n=116,116,114)	-1.13 (± 2.019)	-1.15 (± 1.911)	-1.52 (± 1.895)	
Change -W4 in NBP (n=116,116,114)	-1.05 (± 2.270)	-1.25 (± 1.835)	-1.19 (± 2.082)	
Change -W8 in TBP (n=116,115,114)	-1.80 (± 2.190)	-1.78 (± 2.294)	2.20 (± 2.243)	
Change -W8 in NBP (n=116,115,114)	-1.69 (± 2.264)	-1.85 (± 2.122)	-2.01 (± 2.517)	
Change -W12 in TBP (n=116,115,112)	-1.81 (± 2.295)	-1.70 (± 2.218)	-1.84 (± 2.288)	
Change -W12 in NBP (n=116,115,112)	-1.61 (± 2.342)	-1.79 (± 2.127)	-1.76 (± 2.554)	

Change -W16 in TBP (n=115,116,114)	-1.80 (± 2.374)	-1.87 (± 2.465)	-2.07 (± 2.387)	
Change -W16 in NBP (n=115,116,114)	-1.76 (± 2.506)	-2.02 (± 2.541)	-2.05 (± 2.606)	
Change -W20 in TBP (n=86,92,98)	-2.73 (± 2.456)	-2.74 (± 2.088)	-2.69 (± 2.414)	
Change -W20 in NBP (n=86,92,98)	-2.67 (± 2.602)	-2.73 (± 2.246)	-2.83 (± 2.804)	
Change -W24 in TBP (n=88,95,99)	-2.80 (± 2.528)	-2.90 (± 2.389)	-2.77 (± 2.511)	
Change -W24 in NBP (n=88,94,99)	-2.75 (± 2.597)	-2.79 (± 2.367)	-2.68 (± 2.960)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patients Global Assessment (PGA) Scale Score Through Week 24

End point title	Change From Baseline in Patients Global Assessment (PGA) Scale Score Through Week 24
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End point description:

The Patient's Global Assessment of Disease Activity is one of the components of ASAS 40. It is measured on a VAS (0 to 10 cm; 0 = very well, 10 = very poor). Change from baseline in PGA scale were imputed using early escape rule (The measurement value at Week 20 and Week 24 was set as missing). FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received. Here 'n' signifies number of subjects who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline, Week 4, 8, 12, 16, 20 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n=116,116,114)	-0.99 (± 1.727)	-1.01 (± 1.677)	-1.21 (± 1.645)	
Change at Week 8 (n=116,115,114)	-1.48 (± 2.086)	-1.60 (± 2.039)	-1.70 (± 2.096)	
Change at Week 12 (n=116,115,112)	-1.52 (± 2.043)	-1.53 (± 2.100)	-1.77 (± 2.088)	
Change at Week 16 (n=115,116,114)	-1.64 (± 2.259)	-1.73 (± 2.564)	-1.77 (± 2.293)	
Change at Week 20 (n=86,92,98)	-2.10 (± 2.272)	-2.17 (± 2.225)	-2.36 (± 2.283)	
Change at Week 24 (n=88,95,99)	-2.37 (± 2.298)	-2.55 (± 2.664)	-2.50 (± 2.379)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D Index at Week 16 and 24

End point title	Change From Baseline in EQ-5D Index at Week 16 and 24
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End point description:

The EuroQol-5 is a five dimensional health state classification. Each dimension is assessed on a 3-point ordinal scale (1=no problems, 2=some problems, 3=extreme problems). The responses to the five EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 to 1, with 1.00 indicating "full health" and 0 representing dead. Change from baseline in EQ-5D index were imputed using early escape rule (measurement value at Week 20 and Week 24 was set as missing). FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received. Here 'n' signifies number of subjects who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline, Week 16 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 16 (114,116,113)	0.08 (± 0.138)	0.09 (± 0.154)	0.10 (± 0.139)	
Change at Week 24 (n=87,94,98)	0.12 (± 0.137)	0.12 (± 0.168)	0.13 (± 0.153)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D VAS at Week 16 and 24

End point title	Change From Baseline in EQ-5D VAS at Week 16 and 24
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End point description:

European Quality of Life 5 Dimensions (EQ-5D) visual analog scale (VAS) is a 20 centimeter (cm) vertical VAS with scores ranging from 0 (worst imaginable health) to 100 (perfect health). A higher score indicates an improvement in health in the Health Status Index. Change from baseline in EQ-5D VAS were imputed using early escape rule (measurement value at Week 20 and Week 24 was set as missing). FAS included all subjects who were randomized and received at least one administration of study agent. Subjects analyzed based on randomized treatment group they were assigned to regardless of treatment received. Here 'n' signifies number of subjects who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
End point timeframe:	
Baseline, Week 16 and 24	

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 16 (n=114,116,113)	11.49 (± 20.328)	11.26 (± 23.588)	13.36 (± 22.110)	
Change at Week 24 (n=87,94,98)	17.57 (± 20.251)	13.90 (± 26.132)	16.80 (± 22.181)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Berlin Magnetic Resonance Imaging (MRI) Spine Score at Week 24

End point title	Change From Baseline in Berlin Magnetic Resonance Imaging (MRI) Spine Score at Week 24
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End point description:

The study used MRI with fat-saturating techniques such as short tau inversion recovery (STIR) to look for the presence of bone marrow edema. The Berlin modification of ASspiMRI-a (ASspiMRI-a) scoring technique assesses inflammation in each of the 23 disc vertebral units (DVU), capturing edema and erosion. Scores for each DVU range from 0-3 (0=normal; 1=minor bone marrow edema [less than or equal to 25% of DVU; 3=severe bone marrow edema (more than 50% of DVU)]. The composite score ranges from 0 to 69, with higher scores indicating more severe inflammation. Population included subset of FAS with subjects who did not meet early escape criteria and have both baseline and Week 24 MRI assessments.

End point type	Secondary
End point timeframe:	
Baseline and Week 24	

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	23	18	26	
Units: Units on a scale				
arithmetic mean (standard deviation)	-0.48 (± 2.053)	-0.58 (± 2.343)	-1.15 (± 2.32)	

Statistical analyses

Secondary: Change From Baseline in Percent Work Time Missed Due to AS [Assessed by Work Productivity and Activity Impairment Questionnaire - Specific Health Problem (WPAI-SHP)] Through Week 24

End point title	Change From Baseline in Percent Work Time Missed Due to AS [Assessed by Work Productivity and Activity Impairment Questionnaire - Specific Health Problem (WPAI-SHP)] Through Week 24
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End point description:

WPAI-SHP is 6-item questionnaire used to assess degree to which specified health problem (here AS) affected work attendance, work productivity (WP) and productivity in non-work regular activities. Patients are asked to consider the past 7 days prior to each questionnaire day. Questionnaire asks: current employment status, hours worked, hours missed from work for any reason other than AS, hours missed from work due to AS, degree to which AS affected WP, degree to which AS affected non-work regular activities. 4 component scores were then calculated: percent work time missed due to AS; percent impairment while working due to AS, percent overall work impairment due to AS, percent non-work activity impairment due to AS. Computed percentage range for each sub-scale was 0-100, with higher numbers indicating greater impairment, less productivity. FAS population was included. Here 'n' signifies number of participants who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline, Week 16 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 16 (67,67,70)	-3.72 (± 26.092)	-2.05 (± 26.625)	-2.06 (± 26.486)	
Change at Week 24(n=55,56,62)	-7.37 (± 16.925)	-4.38 (± 22.562)	-7.07 (± 22.081)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Percent Impairment While Working Due to AS (Assessed by WPAI-SHP) Through Week 24

End point title	Change From Baseline in Percent Impairment While Working Due to AS (Assessed by WPAI-SHP) Through Week 24
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End point description:

WPAI-SHP is 6-item questionnaire used to assess degree to which specified health problem (here AS) affected work attendance, work productivity (WP) and productivity in non-work regular activities. Patients are asked to consider the past 7 days prior to each questionnaire day. Questionnaire asks: current employment status, hours worked, hours missed from work for any reason other than AS, hours missed from work due to AS, degree to which AS affected WP, degree to which AS affected non-work regular activities. 4 component scores were then calculated: percent work time missed due to AS; percent impairment while working due to AS, percent overall work impairment due to AS, percent non-work activity impairment due to AS. Computed percentage range for each sub-scale was 0-100, with

higher numbers indicating greater impairment, less productivity. FAS population was included. Here 'n' signifies number of participants who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
End point timeframe:	
Baseline, Week 16 and 24	

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: units on a scale				
arithmetic mean (standard deviation)				
Change at Week 16 (n= 67, 67, 70)	-16.87 (± 25.359)	-5.97 (± 21.607)	-17.57 (± 20.032)	
Change at Week 16 (n= 55, 56, 62)	-22.00 (± 21.892)	-13.57 (± 22.758)	-19.68 (± 22.973)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Percent Overall Work Impairment Due to AS (Assessed by WPAI-SHP) Through Week 24

End point title	Change From Baseline in Percent Overall Work Impairment Due to AS (Assessed by WPAI-SHP) Through Week 24
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End point description:

WPAI-SHP is 6-item questionnaire used to assess degree to which specified health problem (here AS) affected work attendance, work productivity (WP) and productivity in non-work regular activities. Patients are asked to consider the past 7 days prior to each questionnaire day. Questionnaire asks: current employment status, hours worked, hours missed from work for any reason other than AS, hours missed from work due to AS, degree to which AS affected WP, degree to which AS affected non-work regular activities. 4 component scores were then calculated: percent work time missed due to AS; percent impairment while working due to AS, percent overall work impairment due to AS, percent non-work activity impairment due to AS. Computed percentage range for each sub-scale was 0-100, with higher numbers indicating greater impairment, less productivity. FAS population was included. Here 'n' signifies number of participants who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
End point timeframe:	
Baseline, Week 16 and 24	

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: units on a scale				
arithmetic mean (standard deviation)				

Change at Week 16 (67, 67, 70)	-16.03 (± 26.281)	-6.64 (± 23.976)	-17.48 (± 20.811)	
Change at Week 16 (55, 56, 62)	-21.98 (± 21.042)	-14.64 (± 24.300)	-20.54 (± 24.271)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Percent non Work Activity Impairment Due to AS (Assessed by WPAI-SHP) Through Week 24

End point title	Change From Baseline in Percent non Work Activity Impairment Due to AS (Assessed by WPAI-SHP) Through Week 24
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End point description:

WPAI-SHP is 6-item questionnaire used to assess degree to which specified health problem (here AS) affected work attendance, work productivity (WP) and productivity in non-work regular activities. Patients are asked to consider the past 7 days prior to each questionnaire day. Questionnaire asks: current employment status, hours worked, hours missed from work for any reason other than AS, hours missed from work due to AS, degree to which AS affected WP, degree to which AS affected non-work regular activities. 4 component scores were then calculated: percent work time missed due to AS; percent impairment while working due to AS, percent overall work impairment due to AS, percent non-work activity impairment due to AS. Computed percentage range for each sub-scale was 0-100, with higher numbers indicating greater impairment, less productivity. FAS population was included. Here 'n' signifies number of participants who were analyzed at each specified timepoint, for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline, Week 16 and 24

End point values	Placebo	Ustekinumab 45mg	Ustekinumab 90mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	116	114	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 16 (n= 114, 116, 113)	-14.74 (± 23.013)	-13.45 (± 21.833)	-17.52 (± 22.101)	
Change at Week 24 (n= 87, 94, 98)	-21.72 (± 23.288)	-21.49 (± 23.825)	-21.73 (± 22.339)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Approximately 2 years

Adverse event reporting additional description:

The safety analysis set included all participants who received at least 1 (partial or complete) administration of study agent, i.e., the treated population. Adverse events were reported according to the treatment they actually received, regardless of the treatments they are randomized to.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.0
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Subjects received placebo subcutaneous (SC) injection at Weeks 0, 4, and 16. At Week 16, subjects who met EE criteria were administered open-label golimumab 50 milligram (mg) SC administrations at Week 16 and every 4 weeks (q4w) thereafter through Week 52. At Week 24 all subjects (with the exception of subjects who qualified for early escape [EE]) were re-randomized to receive either ustekinumab 45 or 90 milligram (mg) SC injection at Weeks 24 and 28 followed by every 12 weeks (q12w) dosing through Week 100.

Reporting group title	Placebo to Golimumab
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Reporting group description:

Subjects randomized to placebo SC who met early escape criteria and received golimumab from Week 16; adverse events are counted from early escape onward.

Reporting group title	Placebo to Ustekinumab 45mg
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Reporting group description:

Subjects randomized to placebo SC and then rerandomized to receive ustekinumab 45 mg at Week 24; adverse events are counted from crossover onward.

Reporting group title	Placebo to Ustekinumab 90mg
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Reporting group description:

Subjects randomized to placebo SC and then rerandomized to receive ustekinumab 90 mg at Week 24; adverse events are counted from crossover onward.

Reporting group title	Ustekinumab 45mg Only
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Reporting group description:

Subjects received ustekinumab 45 mg SC injection at Weeks 0 and 4, followed by every 12 week dosing, with the last administration of study agent at Week 100. At Week 16, subjects who met EE criteria were administered open-label golimumab 50 mg SC administrations at Week 16 and q4w thereafter through Week 52.

Reporting group title	Ustekinumab 45mg to Golimumab
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Reporting group description:

Subjects randomized to ustekinumab 45 mg SC who met early escape criteria and received golimumab from Week 16; adverse events are counted from early escape onward.

Reporting group title	Ustekinumab 90mg Only
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Reporting group description:

Subjects received ustekinumab 90 mg SC injection at Weeks 0 and 4, followed by q12w dosing, with the last administration of study agent at Week 100. At Week 16, subjects who meet EE criteria were administered open-label golimumab 50 mg SC administrations at Week 16 and q4w thereafter through Week 52.

Reporting group title	Ustekinumab 90mg to Golimumab
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Reporting group description:

Subjects randomized to ustekinumab 90 mg SC who met early escape criteria and received golimumab from Week 16; adverse events are counted from early escape onward.

Serious adverse events	Placebo	Placebo to Golimumab	Placebo to Ustekinumab 45mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 116 (1.72%)	0 / 26 (0.00%)	2 / 44 (4.55%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Salivary Gland Neoplasm			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Back Injury			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	1 / 44 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Sprain			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	1 / 44 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Strain			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	1 / 44 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural Haematoma			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Facial Paralysis			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	1 / 116 (0.86%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebrobasilar Insufficiency			
subjects affected / exposed	1 / 116 (0.86%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Ocular Hypertension			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uveitis			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	1 / 44 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus Urinary			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral Disc Disorder			

subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	1 / 44 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo to Ustekinumab 90mg	Ustekinumab 45mg Only	Ustekinumab 45mg to Golimumab
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 43 (4.65%)	3 / 116 (2.59%)	3 / 21 (14.29%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Salivary Gland Neoplasm			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Back Injury			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Concussion			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Sprain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Strain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural Haematoma			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Facial Paralysis			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebrobasilar Insufficiency			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Ocular Hypertension			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uveitis			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus Urinary			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral Disc Disorder			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ustekinumab 90mg Only	Ustekinumab 90mg to Golimumab	
Total subjects affected by serious adverse events			

subjects affected / exposed	2 / 114 (1.75%)	0 / 14 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Salivary Gland Neoplasm			
subjects affected / exposed	0 / 114 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Back Injury			
subjects affected / exposed	0 / 114 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	0 / 114 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament Sprain			
subjects affected / exposed	0 / 114 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle Strain			
subjects affected / exposed	0 / 114 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural Haematoma			
subjects affected / exposed	1 / 114 (0.88%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Facial Paralysis			
subjects affected / exposed	0 / 114 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Ischaemic Stroke			
subjects affected / exposed	0 / 114 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar Insufficiency			
subjects affected / exposed	0 / 114 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Ocular Hypertension			
subjects affected / exposed	0 / 114 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uveitis			
subjects affected / exposed	0 / 114 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 114 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Calculus Urinary			
subjects affected / exposed	0 / 114 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Intervertebral Disc Disorder			
subjects affected / exposed	0 / 114 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			

subjects affected / exposed	0 / 114 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 114 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	1 / 114 (0.88%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	Placebo to Golimumab	Placebo to Ustekinumab 45mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 116 (12.93%)	4 / 26 (15.38%)	3 / 44 (6.82%)
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	6 / 116 (5.17%)	2 / 26 (7.69%)	1 / 44 (2.27%)
occurrences (all)	6	2	1
Aspartate Aminotransferase Increased			
subjects affected / exposed	3 / 116 (2.59%)	2 / 26 (7.69%)	0 / 44 (0.00%)
occurrences (all)	4	2	0
Musculoskeletal and connective tissue disorders			
Ankylosing Spondylitis			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
Fasciitis			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Acute Sinusitis			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 116 (0.86%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences (all)	1	0	0
Respiratory Tract Infection Viral			
subjects affected / exposed	2 / 116 (1.72%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences (all)	2	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 116 (1.72%)	1 / 26 (3.85%)	0 / 44 (0.00%)
occurrences (all)	2	1	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	5 / 116 (4.31%)	1 / 26 (3.85%)	1 / 44 (2.27%)
occurrences (all)	6	1	1
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 116 (0.00%)	0 / 26 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo to Ustekinumab 90mg	Ustekinumab 45mg Only	Ustekinumab 45mg to Golimumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 43 (0.00%)	24 / 116 (20.69%)	7 / 21 (33.33%)
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 43 (0.00%)	8 / 116 (6.90%)	2 / 21 (9.52%)
occurrences (all)	0	8	2
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 43 (0.00%)	8 / 116 (6.90%)	3 / 21 (14.29%)
occurrences (all)	0	8	3
Musculoskeletal and connective tissue disorders			
Ankylosing Spondylitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Fasciitis			

subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	0 / 116 (0.00%) 0	0 / 21 (0.00%) 0
Infections and infestations			
Acute Sinusitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 43 (0.00%)	2 / 116 (1.72%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 43 (0.00%)	3 / 116 (2.59%)	2 / 21 (9.52%)
occurrences (all)	0	6	2
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 43 (0.00%)	9 / 116 (7.76%)	2 / 21 (9.52%)
occurrences (all)	0	9	2
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 43 (0.00%)	3 / 116 (2.59%)	0 / 21 (0.00%)
occurrences (all)	0	3	0

Non-serious adverse events	Ustekinumab 90mg Only	Ustekinumab 90mg to Golimumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 114 (22.81%)	4 / 14 (28.57%)	
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	6 / 114 (5.26%)	0 / 14 (0.00%)	
occurrences (all)	6	0	
Aspartate Aminotransferase Increased			
subjects affected / exposed	3 / 114 (2.63%)	0 / 14 (0.00%)	
occurrences (all)	3	0	
Musculoskeletal and connective tissue disorders			

Ankylosing Spondylitis subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 14 (7.14%) 1	
Fasciitis subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 14 (7.14%) 1	
Infections and infestations			
Acute Sinusitis subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	1 / 14 (7.14%) 1	
Influenza subjects affected / exposed occurrences (all)	0 / 114 (0.00%) 0	1 / 14 (7.14%) 1	
Respiratory Tract Infection Viral subjects affected / exposed occurrences (all)	6 / 114 (5.26%) 6	0 / 14 (0.00%) 0	
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	4 / 114 (3.51%) 4	0 / 14 (0.00%) 0	
Viral Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	11 / 114 (9.65%) 14	0 / 14 (0.00%) 0	
Metabolism and nutrition disorders			
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1	1 / 14 (7.14%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 August 2015	The main reason of this amendment was to included the following changes: a subset of subjects was to be enrolled in an MRI substudy to explore changes in the Berlin MRI spine score during treatment, an additional chemistry assessment at Week 28 was added, clarification on the informed consents for the microbiome and MRI substudies were made, only subjects participating in the MRI substudy were to undergo MRI assessments, and some minor editorial changes. The Sponsor intended to enroll up to 10% of the study population with total spinal ankyloses.
16 February 2016	The main reason of this amendment was to included the following changes: radiographic progression was added as an efficacy related secondary objective for the study, change in length of the study from Week 64 to Week 112 for subjects who did not meet EE criteria and continued treatment. Subjects who reached Week 64 had the opportunity to decide their participation in the study extension. The added radiographic evaluations (x-ray of cervical and lumbar spine) were to be conducted during the study at baseline and at Week 100, and minor editorial changes.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

The study was discontinued since neither dose achieved the study's primary or major secondary endpoints.

Notes: