



Clinical trial results:

A Phase 3 Multicenter, Randomized, Double-blind, Placebocontrolled Study Evaluating the Efficacy and Safety of Ustekinumab in the Treatment of Adolescent Subjects With Moderate to Severe Plaque-type Psoriasis

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2009-014368-20
Trial protocol	DE NL SE PT FR BE HU GB Outside EU/EEA
Global end of trial date	03 January 2014

Results information

Result version number	v2 (current)
This version publication date	15 July 2016
First version publication date	13 August 2015
Version creation reason	• Correction of full data set Review of data

Trial information

Trial identification

Sponsor protocol code	CNT01275PSO3006
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01090427
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)	Yes
EMA paediatric investigation plan number(s)	EMA-000311-PIP01-08
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	03 January 2014
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	03 January 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of this study was to evaluate the efficacy and safety of 2 Subcutaneous (SC) dosing tiers of ustekinumab in the treatment of adolescent patients greater than equal to (\geq) 12 to less than ($<$) 18 years of age with moderate to severe chronic plaque psoriasis.

Protection of trial subjects:

Safety evaluation in this study included the assessment of adverse events (AEs), vital signs, routine laboratories, C-Reactive Protein (CRP) and cholesterol.

Background therapy:

None

Evidence for comparator:

Placebo

Actual start date of recruitment	30 March 2010
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	Belgium: 11
Country: Number of subjects enrolled	Canada: 41
Country: Number of subjects enrolled	Germany: 2
Country: Number of subjects enrolled	France: 5
Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	Hungary: 7
Country: Number of subjects enrolled	Portugal: 8
Country: Number of subjects enrolled	Russian Federation: 19
Country: Number of subjects enrolled	Sweden: 3
Country: Number of subjects enrolled	Ukraine: 8
Worldwide total number of subjects	110
EEA total number of subjects	42

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)	110
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 110 participants from 10 countries were randomized and treated in this study.

Pre-assignment

Screening details:

A total of 110 participants were randomized into three groups, i.e 37 participants to placebo, 37 participants to ustekinumab half-standard dosage and 36 participants to ustekinumab standard dosage.

Period 1

Period 1 title	Controlled Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo - Controlled Period (CP)

Arm description:

Controlled period (Week 0-12) - Placebo Subcutaneous (SC) injections at Week 0 and 4.

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

Dosage and administration details:

Participants received a subcutaneous (SC) injection of Placebo at Weeks 0 and 4.

Arm title	Ustekinumab Half-Standard Dosage Controlled period (CP)
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Arm description:

Controlled period (Week 0-12) - Ustekinumab Subcutaneous (SC) injections of 0.375 milligram per kilogram (mg/kg) for participants with weight less than equal to (\leq) 60 kilogram (kg), 22.5 milligram (mg) for participants with weight greater than ($>$) 60 to less than equal to (\leq) 100 kg, and 45 mg for participants with weight greater than ($>$) 100 kg at Week 0 and Week 4.

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

Dosage and administration details:

Controlled period (Week 0-12) - Ustekinumab Subcutaneous (SC) injections of 0.375 milligram per kilogram (mg/kg) for participants with weight less than equal to (\leq) 60 kilogram (kg), 22.5 milligram (mg) for participants with weight greater than ($>$) 60 to less than equal to (\leq) 100 kg, and 45 mg for participants with weight greater than ($>$) 100 kg at Week 0 and Week 4.

Arm title	Ustekinumab Standard Dosage Controlled Period (CP)
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Arm description:

Controlled period (Week 0-12) - Ustekinumab Subcutaneous (SC) injections of 0.75 milligram per kilogram (mg/kg) for participants with weight less than equal to (\leq) 60 kilogram (kg), 45 milligram (mg) for participants with weight greater than ($>$) 60 to less than equal to (\leq) 100 kg, and 90 mg for participants with weight $>$ 100 kg at Week 0 and Week 4.

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

Dosage and administration details:

Controlled period (Week 0-12) - Ustekinumab Subcutaneous (SC) injections of 0.75 milligram per kilogram (mg/kg) for participants with weight less than equal to (\leq) 60 kilogram (kg), 45 milligram (mg) for participants with weight greater than ($>$) 60 to 100kg, and 90 mg for participants with weight $>$ 100 kg at Week 0 and Week 4.

Number of subjects in period 1	Placebo - Controlled Period (CP)	Ustekinumab Half-Standard Dosage Controlled period (CP)	Ustekinumab Standard Dosage Controlled Period (CP)
Started	37	37	36
Completed	37	37	36

Period 2

Period 2 title	After Controlled Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo -> Ustekinumab Half-Standard Dosage (after CP)

Arm description:

After Controlled period (Week 12-60) - patients receiving Placebo at Weeks 0 and 4 -> receiving Ustekinumab Half-Standard Dosage at Week 12 and 16 then every 12 week with the last dose at Week 40.

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

Dosage and administration details:

Participants received ustekinumab subcutaneous (SC) injections [0.375 milligram per kilogram (mg/kg), 22.5 milligram (mg), or 45 mg based on body weight] at Weeks 12, 16, 28, and 40.

Arm title	Placebo -> Ustekinumab Standard Dosage (after CP)
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Arm description:

After Controlled period (Week 12-60) - patients receiving Placebo at Weeks 0 and 4 -> receiving Ustekinumab Standard Dosage at Week 12 and 16 then q12wk with last dose at Week 40.

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

Dosage and administration details:

Participants received ustekinumab [0.75 milligram per kilogram (mg/kg), 45 mg, or 90 mg based on body weight] subcutaneous (SC) injections at Weeks 12, 16, 28, and 40.

Arm title	Ustekinumab Half-Standard Dosage (after CP)
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Arm description:

After Controlled period (Week 12-60) - patients receiving Ustekinumab Half-Standard Dosage at Weeks 16, 28 and every 12 weeks with the last dose at Week 40.

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

Dosage and administration details:

Participants received ustekinumab subcutaneous (SC) injections [0.375 milligram per kilogram (mg/kg), 22.5 milligram (mg), or 45 mg based on body weight] at Weeks 16, 28, and 40.

Arm title	Ustekinumab Standard Dosage (after CP)
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Arm description:

After Controlled period (Week 12-60) - patients receiving Ustekinumab Standard Dosage at Weeks 16, 28 and every 12 weeks with last dose at Week 40.

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

Dosage and administration details:

Participants received ustekinumab [0.75 milligram per kilogram (mg/kg), 45 milligram (mg), or 90 mg based on body weight] subcutaneous (SC) injections at Weeks 16, 28, and 40.

Number of subjects in period 2	Placebo -> Ustekinumab Half-Standard Dosage (after CP)	Placebo -> Ustekinumab Standard Dosage (after CP)	Ustekinumab Half-Standard Dosage (after CP)
Started	19	18	37
Completed	17	18	32
Not completed	2	0	5
Adverse event, serious fatal	-	-	1
Adverse event, non-fatal	2	-	1
Lack of efficacy	-	-	3

Number of subjects in period 2	Ustekinumab Standard Dosage (after CP)
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Started	36
Completed	34
Not completed	2
Adverse event, serious fatal	-
Adverse event, non-fatal	-
Lack of efficacy	2

Baseline characteristics

Reporting groups

Reporting group title	Placebo - Controlled Period (CP)
Reporting group description:	
Controlled period (Week 0-12) - Placebo Subcutaneous (SC) injections at Week 0 and 4.	
Reporting group title	Ustekinumab Half-Standard Dosage Controlled period (CP)
Reporting group description:	
Controlled period (Week 0-12) - Ustekinumab Subcutaneous (SC) injections of 0.375 milligram per kilogram (mg/kg) for participants with weight less than equal to (\leq) 60 kilogram (kg), 22.5 milligram (mg) for participants with weight greater than ($>$) 60 to less than equal to (\leq) 100 kg, and 45 mg for participants with weight greater than ($>$) 100 kg at Week 0 and Week 4.	
Reporting group title	Ustekinumab Standard Dosage Controlled Period (CP)
Reporting group description:	
Controlled period (Week 0-12) - Ustekinumab Subcutaneous (SC) injections of 0.75 milligram per kilogram (mg/kg) for participants with weight less than equal to (\leq) 60 kilogram (kg), 45 milligram (mg) for participants with weight greater than ($>$) 60 to less than equal to (\leq) 100 kg, and 90 mg for participants with weight $>$ 100 kg at Week 0 and Week 4.	

Reporting group values	Placebo - Controlled Period (CP)	Ustekinumab Half-Standard Dosage Controlled period (CP)	Ustekinumab Standard Dosage Controlled Period (CP)
Number of subjects	37	37	36
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	37	37	36
Adults (18-64 years)	0	0	0
From 65 to 84 years	0	0	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	15.6	15.1	14.8
standard deviation	± 1.46	± 1.7	± 1.73
Title for Gender Units: subjects			
Female	17	19	20
Male	20	18	16

Reporting group values	Total		
Number of subjects	110		
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	110		
Adults (18-64 years)	0		
From 65 to 84 years	0		
85 years and over	0		

Title for AgeContinuous Units: years arithmetic mean standard deviation	-		
Title for Gender Units: subjects			
Female	56		
Male	54		

End points

End points reporting groups

Reporting group title	Placebo - Controlled Period (CP)
Reporting group description: Controlled period (Week 0-12) - Placebo Subcutaneous (SC) injections at Week 0 and 4.	
Reporting group title	Ustekinumab Half-Standard Dosage Controlled period (CP)
Reporting group description: Controlled period (Week 0-12) - Ustekinumab Subcutaneous (SC) injections of 0.375 milligram per kilogram (mg/kg) for participants with weight less than equal to (\leq) 60 kilogram (kg), 22.5 milligram (mg) for participants with weight greater than ($>$) 60 to less than equal to (\leq) 100 kg, and 45 mg for participants with weight greater than ($>$) 100 kg at Week 0 and Week 4.	
Reporting group title	Ustekinumab Standard Dosage Controlled Period (CP)
Reporting group description: Controlled period (Week 0-12) - Ustekinumab Subcutaneous (SC) injections of 0.75 milligram per kilogram (mg/kg) for participants with weight less than equal to (\leq) 60 kilogram (kg), 45 milligram (mg) for participants with weight greater than ($>$) 60 to less than equal to (\leq) 100 kg, and 90 mg for participants with weight $>$ 100 kg at Week 0 and Week 4.	
Reporting group title	Placebo -> Ustekinumab Half-Standard Dosage (after CP)
Reporting group description: After Controlled period (Week 12-60) - patients receiving Placebo at Weeks 0 and 4 -> receiving Ustekinumab Half-Standard Dosage at Week 12 and 16 then every 12 week with the last dose at Week 40.	
Reporting group title	Placebo -> Ustekinumab Standard Dosage (after CP)
Reporting group description: After Controlled period (Week 12-60) - patients receiving Placebo at Weeks 0 and 4 -> receiving Ustekinumab Standard Dosage at Week 12 and 16 then q12wk with last dose at Week 40.	
Reporting group title	Ustekinumab Half-Standard Dosage (after CP)
Reporting group description: After Controlled period (Week 12-60) - patients receiving Ustekinumab Half-Standard Dosage at Weeks 16, 28 and every 12 weeks with the last dose at Week 40.	
Reporting group title	Ustekinumab Standard Dosage (after CP)
Reporting group description: After Controlled period (Week 12-60) - patients receiving Ustekinumab Standard Dosage at Weeks 16, 28 and every 12 weeks with last dose at Week 40.	

Primary: The Percentage of Participants Achieving a Physician's Global Assessment (PGA) Score of Cleared (0) or Minimal (1) at Week 12

End point title	The Percentage of Participants Achieving a Physician's Global Assessment (PGA) Score of Cleared (0) or Minimal (1) at Week 12
End point description: The PGA documents the physician's assessment of the participant's psoriasis status according to the following categories: induration, scaling, and erythema. The participant's psoriasis is assessed as 6-point scale as follows: cleared (0), minimal (1), mild (2), moderate (3), marked (4), or severe (5); higher score indicates worse disease. The table below shows the percentage of participants who achieved a PGA score of 0 or 1 at Week 12 in each treatment group.	
End point type	Primary
End point timeframe: Week 12	

End point values	Placebo - Controlled Period (CP)	Ustekinumab Half-Standard Dosage Controlled period (CP)	Ustekinumab Standard Dosage Controlled Period (CP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	37	36	
Units: Percentage of Participants				
number (not applicable)	5.4	67.6	69.4	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: The Percentage of Participants Achieving a Physician's Global Assessment (PGA) Score of Cleared (0) or Minimal (1) at Week 12.	
Comparison groups	Ustekinumab Half-Standard Dosage Controlled period (CP) v Placebo - Controlled Period (CP)
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: The Percentage of Participants Achieving a Physician's Global Assessment (PGA) Score of Cleared (0) or Minimal (1) at Week 12	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Standard Dosage Controlled Period (CP)
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: The Percentage of Participants Achieving a Psoriasis Area and Severity Index (PASI) 75 Response at Week 12

End point title	The Percentage of Participants Achieving a Psoriasis Area and Severity Index (PASI) 75 Response at Week 12
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End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 to 72, with higher scores indicating worse disease. A PASI 75 response is defined as a equal to or greater than (\geq) 75%

improvement in PASI score from baseline. The table below shows the percentage of participants who achieved a PASI 75 response at Week 12 in each treatment group.

End point type	Secondary
End point timeframe:	
Week 12	

End point values	Placebo - Controlled Period (CP)	Ustekinumab Half-Standard Dosage Controlled period (CP)	Ustekinumab Standard Dosage Controlled Period (CP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	37	36	
Units: Percentage of Participants				
number (not applicable)	10.8	78.4	80.6	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
The Percentage of Participants Achieving a Psoria Area and Severity Index (PASI) 75 Response at Week 12.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Half-Standard Dosage Controlled period (CP)
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
The Percentage of Participants Achieving a Psoriasis Area and Severity Index (PASI) 75 Response at Week 12.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Standard Dosage Controlled Period (CP)
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Change From Baseline in Children's Dermatology Life Quality Index (CDLQI) Score at Week 12 Compared Between the Placebo Group and the

Ustekinumab Treatment Groups

End point title	Change From Baseline in Children's Dermatology Life Quality Index (CDLQI) Score at Week 12 Compared Between the Placebo Group and the Ustekinumab Treatment Groups
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End point description:

The CDLQI is a dermatology-specific quality of life instrument designed to assess the impact of the disease on a child's quality of life. The CDLQI, a 10-item questionnaire has 4 items response options and a recall period of 1 week. In addition to evaluating overall quality of life, the CDLQI can be used to assess 6 different aspects that may affect quality of life: symptoms and feelings, leisure, School or holidays, personal relationships, sleep, and treatment. The CDLQI is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0; the higher the score, the greater impairment in quality of life. The table below shows the mean change in CDLQI score from baseline at Week 12 for each treatment group.

End point type	Secondary
End point timeframe:	
Baseline; Week 12	

End point values	Placebo - Controlled Period (CP)	Ustekinumab Half-Standard Dosage Controlled period (CP)	Ustekinumab Standard Dosage Controlled Period (CP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	32	35	32	
Units: Scores on a scale				
arithmetic mean (standard deviation)	-1.5 (± 3.18)	-5.6 (± 6.43)	-6.7 (± 5.63)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
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Statistical analysis description:

Change From Baseline in Children's Dermatology Life Quality Index (CDLQI) Score at Week 12 Compared Between the Placebo Group and the Ustekinumab Treatment Groups.

Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Half-Standard Dosage Controlled period (CP)
Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	ANOVA on van der Waerden normal Score

Statistical analysis title	Statistical Analysis 2
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Statistical analysis description:

Change From Baseline in Children's Dermatology Life Quality Index (CDLQI) Score at Week 12 Compared Between the Placebo Group and the Ustekinumab Treatment Groups.

Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Standard Dosage Controlled Period (CP)
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Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANOVA on van der Waerden normal Score

Secondary: The Percentage of Participants Achieving a Psoriasis Area and Severity Index (PASI) 90 Response at Week 12 Compared Between the Placebo Group and the Ustekinumab Treatment Groups

End point title	The Percentage of Participants Achieving a Psoriasis Area and Severity Index (PASI) 90 Response at Week 12 Compared Between the Placebo Group and the Ustekinumab Treatment Groups
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End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 to 72, with higher scores indicating worse disease. The table below shows the percentage of participants who achieved a PASI 90 response defined as achieving a greater than or equal to (\geq) 90% improvement in PASI score from baseline.

End point type	Secondary
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End point timeframe:

Week 12

End point values	Placebo - Controlled Period (CP)	Ustekinumab Half-Standard Dosage Controlled period (CP)	Ustekinumab Standard Dosage Controlled Period (CP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	37	36	
Units: Percentage of Participants				
number (not applicable)	5.4	54.1	61.1	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
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Statistical analysis description:

The Percentage of Participants Achieving a Psoriasis Area and Severity Index (PASI) 90 Response at Week 12 Compared Between the Placebo Group and the Ustekinumab Treatment Groups.

Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Half-Standard Dosage Controlled period (CP)
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: The Percentage of Participants Achieving a Psoriasis Area and Severity Index (PASI) 90 Response at Week 12 Compared Between the Placebo Group and the Ustekinumab Treatment Groups.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Standard Dosage Controlled Period (CP)
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: The Percentage of Participants Achieving a Physician's Global Assessment (PGA) Score of Cleared (0) and PGA Score of Mild or Better (≤ 2) at Week 12

End point title	The Percentage of Participants Achieving a Physician's Global Assessment (PGA) Score of Cleared (0) and PGA Score of Mild or Better (≤ 2) at Week 12
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End point description:

The PGA documents the physician's assessment of the participant's psoriasis status according to the following categories: induration, scaling, and erythema. The participant's psoriasis is assessed as 5-point scale as follows: cleared (0), minimal (1), mild (2), moderate (3), or severe (4); higher score indicates worse disease. The table below shows the percentage of participants who achieved a PGA score of 0 and the percentage of participants who achieved a PGA score of 0, 1, or 2 at Week 12 in each treatment group.

End point type	Secondary
End point timeframe:	
Week 12	

End point values	Placebo - Controlled Period (CP)	Ustekinumab Half-Standard Dosage Controlled period (CP)	Ustekinumab Standard Dosage Controlled Period (CP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	37	36	
Units: Percentage of participants				
number (not applicable)				
PGA of 0	2.7	32.4	47.2	
PGA of 0, 1, or 2	32.4	81.1	83.3	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: The Percentage of Participants Achieving a Physician's Global Assessment (PGA) Score of Cleared (0) at Week 12.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Half-Standard Dosage Controlled period (CP)
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: The Percentage of Participants Achieving a Physician's Global Assessment (PGA) Score of Cleared (0) at Week 12.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Half-Standard Dosage Controlled period (CP)
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 3
Statistical analysis description: The Percentage of Participants Achieving a Physician's Global Assessment (PGA) Score of Mild or Better (<=2) at Week 12.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Half-Standard Dosage Controlled period (CP)
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 4
Statistical analysis description: The Percentage of Participants Achieving a Physician's Global Assessment (PGA) Score of Mild or Better (<=2) at Week 12.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Standard Dosage Controlled Period (CP)

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: The Percentage of Participants Who Were PASI 50 Responders and the Percentage of Participants With a PASI Score of 0 at Week 12

End point title	The Percentage of Participants Who Were PASI 50 Responders and the Percentage of Participants With a PASI Score of 0 at Week 12
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End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). The table below shows the percentage of participants in each treatment group who were PASI 50 responders at Week 12 defined as participants who achieved a greater than or equal to (\geq) 50% improvement in PASI score from baseline as well as the percentage of participants with a PASI score of 0.

End point type	Secondary
End point timeframe:	
Week 12	

End point values	Placebo - Controlled Period (CP)	Ustekinumab Half-Standard Dosage Controlled period (CP)	Ustekinumab Standard Dosage Controlled Period (CP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	37	36	
Units: Percentage of participants				
number (not applicable)				
PASI 50 responders	29.7	81.1	88.9	
Participants with PASI score of 0	2.7	21.6	38.9	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
The Percentage of Participants Who Were PASI 50 Responders.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Half-Standard Dosage Controlled period (CP)

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: The Percentage of Participants Who Were PASI 50 Responders at Week 12.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Standard Dosage Controlled Period (CP)
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 3
Statistical analysis description: The Percentage of Participants With a PASI Score of 0 at Week 12.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Half-Standard Dosage Controlled period (CP)
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.014
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 4
Statistical analysis description: The Percentage of Participants With a PASI Score of 0 at Week 12.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Standard Dosage Controlled Period (CP)
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: The Change From Baseline in Pediatric Quality of Life Inventory (PedsQL) Total Scale Score, Psychosocial Health Summary Score, and Physical Health Summary Score at Week 12

End point title	The Change From Baseline in Pediatric Quality of Life Inventory (PedsQL) Total Scale Score, Psychosocial Health Summary Score, and Physical Health Summary Score at Week 12
End point description:	
<p>The PedsQL is a general health-related quality of life measure developed for use in children and adolescent populations. The Generic Core Scale contains 23 items and is comprised of 4 domains: physical, social, emotional, and school functioning. Each domain can be scored independently. Additionally, a Psychosocial Health and Physical Health Summary Score can be calculated as well as a total score. The measure distinguishes between healthy children and children with acute and chronic health conditions and disease severity within a chronic health condition. The measure is applicable for healthy school and community populations, as well as with pediatric populations with acute and chronic health conditions and has versions for both parent and teen report. Scores range from 0 to 100, and higher scores indicate better health related quality of life.</p>	
End point type	Secondary
End point timeframe:	
Week 12	

End point values	Placebo - Controlled Period (CP)	Ustekinumab Half-Standard Dosage Controlled period (CP)	Ustekinumab Standard Dosage Controlled Period (CP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	36	36	
Units: Scores on a scale				
arithmetic mean (standard deviation)				
PedsQL Total scale score	3.35 (± 10.044)	10.81 (± 12.882)	8.03 (± 10.436)	
PedsQL Psychosocial health summary score	3.66 (± 9.61)	12.13 (± 15.153)	8.43 (± 11.812)	
PedsQL Physical health summary score	2.86 (± 12.86)	8.33 (± 11.378)	7.29 (± 13.446)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Change From Baseline in Pediatric Quality of Life Inventory (PedsQL) Total Scale Score.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Half-Standard Dosage Controlled period (CP)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	ANOVA on van der Waerden normal Score

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Change From Baseline in Pediatric Quality of Life Inventory (PedsQL) Total Scale Score.	

Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Standard Dosage Controlled Period (CP)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.028
Method	ANOVA on van der Waerden normal Score

Statistical analysis title	Statistical Analysis 3
Statistical analysis description: Change From Baseline in Pediatric Quality of Life Inventory (PedsQL) Psychosocial Health Summary Score.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Half-Standard Dosage Controlled period (CP)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	ANOVA on van der Waerden normal Score

Statistical analysis title	Statistical Analysis 4
Statistical analysis description: Change From Baseline in Pediatric Quality of Life Inventory (PedsQL) Psychosocial Health Summary Score.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Standard Dosage Controlled Period (CP)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.063
Method	ANOVA on van der Waerden normal Score

Statistical analysis title	Statistical Analysis 5
Statistical analysis description: Change From Baseline in Pediatric Quality of Life Inventory (PedsQL) Physical Health Summary Score at Week 12.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Half-Standard Dosage Controlled period (CP)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	ANOVA on van der Waerden normal Score

Statistical analysis title	Statistical Analysis 6
Statistical analysis description: Change From Baseline in Pediatric Quality of Life Inventory (PedsQL) Physical Health Summary Score at Week 12.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Standard Dosage Controlled Period (CP)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.02
Method	ANOVA on van der Waerden normal Score

Secondary: The Percentage of Participants With CDLQI Scores of 0 or 1 at Week 12 for Randomized Participants With a Baseline CDLQI Score > 1

End point title	The Percentage of Participants With CDLQI Scores of 0 or 1 at Week 12 for Randomized Participants With a Baseline CDLQI Score > 1
End point description: Efficacy evaluable subjects defined as the subset of all randomized participants with evaluable outcome measurements. In addition, this analysis was limited to participants with a CDLQI of > 1 at baseline	
End point type	Secondary
End point timeframe: Week 12	

End point values	Placebo - Controlled Period (CP)	Ustekinumab Half-Standard Dosage Controlled period (CP)	Ustekinumab Standard Dosage Controlled Period (CP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	30	31	30	
Units: Percentage of participants				
number (not applicable)	13.3	38.7	56.7	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: The Percentage of Participants With CDLQI Scores of 0 or 1 at Week 12 for Randomized Participants With a Baseline CDLQI Score > 1.	
Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Half-Standard Dosage Controlled period (CP)

Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.027
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 2
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Statistical analysis description:

The Percentage of Participants With CDLQI Scores of 0 or 1 at Week 12 for Randomized Participants With a Baseline CDLQI Score > 1.

Comparison groups	Placebo - Controlled Period (CP) v Ustekinumab Standard Dosage Controlled Period (CP)
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Through Week 60

Adverse event reporting additional description:

Adverse events are provided in the tables below for the 110 participants during 2 time periods in the study: during Weeks 0-12 and during Weeks 12-60.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	16.0
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Reporting groups

Reporting group title	Ustekinumab Half-Standard Dosage (CP)
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Reporting group description:

Controlled period (Week 0-12) - Ustekinumab Subcutaneous (SC) injections of 0.375 milligram per kilogram (mg/kg) for patients with weight less than equal to (\leq) 60 kg, 22.5 milligram (mg) for patients with weight greater than ($>$) 60 to \leq 100 kg, and 45 mg for patients with weight $>$ 100 kg at Week 0 and 4.

Reporting group title	Placebo (CP)
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Reporting group description:

Controlled period (Week 0-12) - Placebo Subcutaneous (SC) injections at Week 0 and 4.

Reporting group title	Ustekinumab Standard Dosage (CP)
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Reporting group description:

Controlled period (Week 0-12) - Ustekinumab Subcutaneous (SC) injections of 0.75 milligram per kilogram (mg/kg) for patients with weight less than equal to (\leq) 60 kg, 45 milligram (mg) for patients with weight greater than ($>$) 60 to \leq 100 kg, and 90 mg for patients with weight $>$ 100 kg at Week 0 and 4.

Reporting group title	Placebo -> Ustekinumab Half-Standard Dosage (after CP)
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Reporting group description:

After Controlled period (Week 12-60) - patients receiving Placebo at Weeks 0 and 4 -> receiving Ustekinumab Half-Standard Dosage at Week 12 and 16 then q12w with the last dose at Week 40.

Reporting group title	Ustekinumab Standard Dosage (after CP)
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Reporting group description:

After Controlled period (Week 12-60) - patients receiving Ustekinumab Standard Dosage at Weeks 0 and 4 -> receiving Ustekinumab Standard Dosage q12wk with last dose at Week 40.

Reporting group title	Ustekinumab Half-Standard Dosage (after CP)
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Reporting group description:

After Controlled period (Week 12-60) - patients receiving Ustekinumab Half-Standard Dosage at Weeks 0 and 4 -> receiving Ustekinumab Half-Standard Dosage q12wk with the last dose at Week 40.

Reporting group title	Placebo -> Ustekinumab Standard Dosage (after CP)
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Reporting group description:

After Controlled period (Week 12-60) - patients receiving Placebo at Weeks 0 and 4 -> receiving Ustekinumab Standard Dosage at Week 12 and 16 then q12wk with last dose at Week 40.

Serious adverse events	Ustekinumab Half-Standard Dosage (CP)	Placebo (CP)	Ustekinumab Standard Dosage (CP)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 37 (2.70%)	0 / 37 (0.00%)	0 / 36 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Injury			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (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
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (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
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	1 / 37 (2.70%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis Contact			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (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			
Ear Infection			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (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
Pyelonephritis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (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 -> Ustekinumab Half- Standard Dosage (after CP)	Ustekinumab Standard Dosage (after CP)	Ustekinumab Half- Standard Dosage (after CP)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	5 / 37 (13.51%)
number of deaths (all causes)	0	0	1

number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Injury			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis Contact			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Ear Infection			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	0 / 37 (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
Pyelonephritis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serious adverse events	Placebo -> Ustekinumab Standard Dosage (after CP)		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 18 (0.00%)		
number of deaths (all causes)	0		

number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Injury			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermatitis Contact			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Ear Infection			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Ustekinumab Half-Standard Dosage (CP)	Placebo (CP)	Ustekinumab Standard Dosage (CP)
Total subjects affected by non-serious adverse events subjects affected / exposed	15 / 37 (40.54%)	17 / 37 (45.95%)	13 / 36 (36.11%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Skin Papilloma subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Vascular disorders Orthostatic Hypotension subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all) Oedema Peripheral subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 1 0 / 37 (0.00%) 0 0 / 37 (0.00%) 0	2 / 37 (5.41%) 2 1 / 37 (2.70%) 1 0 / 37 (0.00%) 0	1 / 36 (2.78%) 1 0 / 36 (0.00%) 0 0 / 36 (0.00%) 0
Reproductive system and breast disorders Gynaecomastia subjects affected / exposed occurrences (all) Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0 0 / 37 (0.00%) 0	0 / 37 (0.00%) 0 0 / 37 (0.00%) 0	1 / 36 (2.78%) 1 2 / 36 (5.56%) 3
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Dyspnoea Exertional subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0 0 / 37 (0.00%) 0	0 / 37 (0.00%) 0 0 / 37 (0.00%) 0	1 / 36 (2.78%) 1 0 / 36 (0.00%) 0

Epistaxis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Rhinitis Allergic			
subjects affected / exposed	0 / 37 (0.00%)	1 / 37 (2.70%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal Pain			
subjects affected / exposed	1 / 37 (2.70%)	0 / 37 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Upper-Airway Cough Syndrome			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Investigations			
Haematocrit Decreased			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Lymph Node Palpable			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Haemoglobin Decreased			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Weight Increased			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Arthropod Bite subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Joint Injury subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Muscle Strain subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Skin Injury subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Sunburn subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Thermal Burn subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Nervous system disorders Convulsion subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	4 / 37 (10.81%) 6	2 / 37 (5.41%) 2	3 / 36 (8.33%) 3
Migraine subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	1 / 37 (2.70%) 1	0 / 36 (0.00%) 0
Blood and lymphatic system disorders Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	2 / 37 (5.41%) 2	0 / 36 (0.00%) 0
Monocytosis subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Eye disorders			

Blepharitis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Eye Pruritus			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain			
subjects affected / exposed	1 / 37 (2.70%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Abdominal Pain Lower			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Dental Caries			
subjects affected / exposed	1 / 37 (2.70%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Abdominal Pain Upper			
subjects affected / exposed	1 / 37 (2.70%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Food Poisoning			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Lip Oedema			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			

subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Odynophagia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Tooth Deposit			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Tooth Impacted			
subjects affected / exposed	0 / 37 (0.00%)	1 / 37 (2.70%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 37 (2.70%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Erythema Multiforme			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Night Sweats			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 37 (2.70%)	0 / 37 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Psoriasis			
subjects affected / exposed	0 / 37 (0.00%)	2 / 37 (5.41%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Pain			

subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Back Pain			
subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 1	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Tendonitis			
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Psoriatic Arthropathy			
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	1 / 37 (2.70%) 1	0 / 36 (0.00%) 0
Infections and infestations			
Bacterial Rhinitis			
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Body Tinea			
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Gastroenteritis			
subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 1	1 / 37 (2.70%) 1	0 / 36 (0.00%) 0
Bronchitis			
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	1 / 37 (2.70%) 1	1 / 36 (2.78%) 2
Gingivitis			
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Herpes Simplex			
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Herpes Zoster			
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	0 / 36 (0.00%) 0
Influenza			
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 37 (0.00%) 0	1 / 36 (2.78%) 1

Laryngitis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	5 / 37 (13.51%)	10 / 37 (27.03%)	1 / 36 (2.78%)
occurrences (all)	5	14	1
Oral Herpes			
subjects affected / exposed	1 / 37 (2.70%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Otitis Externa			
subjects affected / exposed	0 / 37 (0.00%)	1 / 37 (2.70%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Pharyngitis			
subjects affected / exposed	3 / 37 (8.11%)	0 / 37 (0.00%)	1 / 36 (2.78%)
occurrences (all)	3	0	1
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Tooth Abscess			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Tooth Infection			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Toxoplasmosis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 37 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 37 (2.70%)	2 / 37 (5.41%)	3 / 36 (8.33%)
occurrences (all)	1	2	4

Non-serious adverse events	Placebo -> Ustekinumab Half- Standard Dosage (after CP)	Ustekinumab Standard Dosage (after CP)	Ustekinumab Half- Standard Dosage (after CP)
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Total subjects affected by non-serious adverse events subjects affected / exposed	15 / 19 (78.95%)	23 / 36 (63.89%)	28 / 37 (75.68%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Skin Papilloma subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 36 (0.00%) 0	1 / 37 (2.70%) 2
Vascular disorders Orthostatic Hypotension subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 36 (0.00%) 0	0 / 37 (0.00%) 0
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all) Oedema Peripheral subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1 0 / 19 (0.00%) 0 1 / 19 (5.26%) 1	0 / 36 (0.00%) 0 0 / 36 (0.00%) 0 1 / 36 (2.78%) 2	0 / 37 (0.00%) 0 1 / 37 (2.70%) 1 1 / 37 (2.70%) 1
Reproductive system and breast disorders Gynaecomastia subjects affected / exposed occurrences (all) Dysmenorrhoea subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1 1 / 19 (5.26%) 1	0 / 36 (0.00%) 0 3 / 36 (8.33%) 8	0 / 37 (0.00%) 0 0 / 37 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Dyspnoea Exertional subjects affected / exposed occurrences (all) Epistaxis	0 / 19 (0.00%) 0 0 / 19 (0.00%) 0	1 / 36 (2.78%) 1 0 / 36 (0.00%) 0	3 / 37 (8.11%) 4 0 / 37 (0.00%) 0

subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Rhinitis Allergic			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal Pain			
subjects affected / exposed	3 / 19 (15.79%)	0 / 36 (0.00%)	3 / 37 (8.11%)
occurrences (all)	3	0	5
Rhinorrhoea			
subjects affected / exposed	2 / 19 (10.53%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	2	0	0
Upper-Airway Cough Syndrome			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Investigations			
Haematocrit Decreased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Lymph Node Palpable			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Haemoglobin Decreased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Weight Increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Arthropod Bite			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	2	0	0
Joint Injury			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Muscle Strain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Skin Injury			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Thermal Burn			
subjects affected / exposed	1 / 19 (5.26%)	1 / 36 (2.78%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Nervous system disorders			
Convulsion			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	2 / 19 (10.53%)	2 / 36 (5.56%)	9 / 37 (24.32%)
occurrences (all)	2	2	19
Migraine			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Monocytosis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Eye disorders			

Blepharitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Eye Pruritus			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Abdominal Pain			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	3 / 37 (8.11%)
occurrences (all)	0	2	5
Abdominal Pain Lower			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Dental Caries			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	3
Abdominal Pain Upper			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	2
Food Poisoning			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Lip Oedema			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	3	0	0
Gastroesophageal Reflux Disease			

subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	3 / 37 (8.11%)
occurrences (all)	0	1	3
Tooth Deposit			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Tooth Impacted			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Erythema Multiforme			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Night Sweats			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 19 (0.00%)	0 / 36 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
Psoriasis			
subjects affected / exposed	1 / 19 (5.26%)	1 / 36 (2.78%)	3 / 37 (8.11%)
occurrences (all)	1	1	4
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Musculoskeletal Pain			

subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 36 (0.00%) 0	0 / 37 (0.00%) 0
Back Pain subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	2 / 36 (5.56%) 2	2 / 37 (5.41%) 3
Tendonitis subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 36 (0.00%) 0	2 / 37 (5.41%) 2
Psoriatic Arthropathy subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 36 (0.00%) 0	0 / 37 (0.00%) 0
Infections and infestations			
Bacterial Rhinitis subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	1 / 36 (2.78%) 1	0 / 37 (0.00%) 0
Body Tinea subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 36 (0.00%) 0	0 / 37 (0.00%) 0
Gastroenteritis subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	1 / 36 (2.78%) 1	0 / 37 (0.00%) 0
Bronchitis subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 2	1 / 36 (2.78%) 2	0 / 37 (0.00%) 0
Gingivitis subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 36 (0.00%) 0	1 / 37 (2.70%) 1
Herpes Simplex subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 36 (0.00%) 0	0 / 37 (0.00%) 0
Herpes Zoster subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 36 (0.00%) 0	0 / 37 (0.00%) 0
Influenza subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 2	0 / 36 (0.00%) 0	0 / 37 (0.00%) 0

Laryngitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 36 (2.78%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	5 / 19 (26.32%)	11 / 36 (30.56%)	11 / 37 (29.73%)
occurrences (all)	9	12	22
Oral Herpes			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	5
Otitis Externa			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	1 / 19 (5.26%)	2 / 36 (5.56%)	2 / 37 (5.41%)
occurrences (all)	2	4	2
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Rhinitis			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	2 / 37 (5.41%)
occurrences (all)	0	2	2
Tooth Abscess			
subjects affected / exposed	0 / 19 (0.00%)	2 / 36 (5.56%)	1 / 37 (2.70%)
occurrences (all)	0	2	1
Tooth Infection			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Toxoplasmosis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 19 (10.53%)	3 / 36 (8.33%)	4 / 37 (10.81%)
occurrences (all)	3	6	6

Non-serious adverse events	Placebo -> Ustekinumab Standard Dosage (after CP)		
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Total subjects affected by non-serious adverse events subjects affected / exposed	13 / 18 (72.22%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Skin Papilloma subjects affected / exposed occurrences (all)	2 / 18 (11.11%) 2		
Vascular disorders Orthostatic Hypotension subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all) Oedema Peripheral subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0 1 / 18 (5.56%) 1 0 / 18 (0.00%) 0		
Reproductive system and breast disorders Gynaecomastia subjects affected / exposed occurrences (all) Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0 0 / 18 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Dyspnoea Exertional subjects affected / exposed occurrences (all) Epistaxis	0 / 18 (0.00%) 0 1 / 18 (5.56%) 1		

subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Rhinitis Allergic			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Oropharyngeal Pain			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Upper-Airway Cough Syndrome			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Depression			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Investigations			
Haematocrit Decreased			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Lymph Node Palpable			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Haemoglobin Decreased			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Weight Increased			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			

Arthropod Bite subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Joint Injury subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Muscle Strain subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Skin Injury subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Sunburn subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Thermal Burn subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Nervous system disorders Convulsion subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Headache subjects affected / exposed occurrences (all)	3 / 18 (16.67%) 6		
Migraine subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Blood and lymphatic system disorders Lymphadenopathy subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1		
Monocytosis subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Eye disorders			

Blepharitis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Eye Pruritus			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Abdominal Pain			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Abdominal Pain Lower			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Dental Caries			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Abdominal Pain Upper			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Food Poisoning			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Lip Oedema			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Gastroesophageal Reflux Disease			

subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Odynophagia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Tooth Deposit			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Tooth Impacted			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Erythema Multiforme			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	2		
Night Sweats			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Psoriasis			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 18 (11.11%)		
occurrences (all)	2		
Musculoskeletal Pain			

subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Back Pain			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Tendonitis			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Psoriatic Arthropathy			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	4		
Infections and infestations			
Bacterial Rhinitis			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Body Tinea			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	2		
Gastroenteritis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Gingivitis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Herpes Simplex			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Herpes Zoster			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		

Laryngitis			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	10 / 18 (55.56%)		
occurrences (all)	16		
Oral Herpes			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Otitis Externa			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Rhinitis			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Tooth Abscess			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Tooth Infection			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Toxoplasmosis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 18 (16.67%)		
occurrences (all)	6		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 December 2010	The overall reason for the amendment was to include changes : Clarification of topical medications/treatments that could affect psoriasis or PASI evaluation: Picrolimus and tacrolimus are topical therapies that may be used in the treatment of psoriasis and concomitant use of these therapies could affect PASI evaluations and present potential safety concerns. Both of these medications were added to the list of medication/treatments that were not permitted within 2 weeks of the first administration of study agent and through Week 60. In addition, the exception clause of allowing subjects to enter the study if they had used low potency corticosteroids on the face and/or groin was removed to allow for a full evaluation of psoriasis on all affected body areas and to avoid any potential confounding of efficacy by previous topical use. It also included other clarifications in the conduct of the study and some minor editorial changes.
06 January 2011	The overall reason for the amendment was to include changes in inclusion criterion regarding previous psoriasis treatments for participants in Germany: The German Central Ethics Committee indicated that local law requires that study participants must have received previous treatment with at least one systemic therapy prior to being enrolled in this study. Therefore, inclusion criterion #3 regarding prior treatments received for psoriasis was changed to comply with local regulations.
27 October 2011	The overall reason for the amendment was to include changes: Removal of collection of whole blood sample for messenger ribonucleic acid (RNA) profiling: As requested per the Hungarian Ethics Committee, differential gene expression (messenger RNA) profiling was not performed for subjects recruited in Hungary.
16 February 2012	The overall reason for the amendment was to include changes: The name of the sponsor for this protocol was changed to Janssen Research & Development: This change was necessary due to a change in the corporate identity of the sponsor. Centocor Research & Development, Inc. operates under the new sponsor identity of Janssen Research & Development and the legal identity of Janssen Research and Development, L.L.C.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported