Clinical trial results:
A Phase 3, Multicenter, Double-Blind, Randomized, Parallel-Arm, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Adalimumab for Treatment of Nail Psoriasis in Patients with Chronic Plaque Psoriasis

Summary

EudraCT number	2013-003275-36
Trial protocol	GR DE BE FR
Global end of trial date	27 April 2016

Results information

Result version number	v1 (current)
This version publication date	11 May 2017
First version publication date	11 May 2017

Trial information

Trial identification

Sponsor protocol code	M13-674

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02016482
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AbbVie Deutschland GmbH & Co.KG
Sponsor organisation address	AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6-4UB
Public contact	Carol A Kotkin, BS, AbbVie, carol.kotkin@abbvie.com
Scientific contact	David Williams, MD, AbbVie, david.williams@abbvie.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	27 April 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 April 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study was conducted to assess the safety and efficacy of adalimumab in subjects with nail psoriasis.

Protection of trial subjects:

Participant and/or legal guardian read and understood the information provided about the study and gave written permission.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 January 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 26
Country: Number of subjects enrolled	Belgium: 17
Country: Number of subjects enrolled	Canada: 50
Country: Number of subjects enrolled	France: 21
Country: Number of subjects enrolled	Germany: 22
Country: Number of subjects enrolled	Greece: 24
Country: Number of subjects enrolled	Puerto Rico: 1
Country: Number of subjects enrolled	United States: 56
Worldwide total number of subjects	217
EEA total number of subjects	84

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)	199
From 65 to 84 years	18
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study included a 3- to 35-day screening period.

Period 1

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

Blinding implementation details:

All AbbVie personnel with direct oversight of the conduct and management of the trial (with the exception of AbbVie Drug Supply Management Team), the Investigator, study site personnel and the subject were to remain blinded to each subject's treatment throughout the blinded period of the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Period A: Placebo subcutaneous every other week (sc eow) for 25 weeks. Period B: Adalimumab (ADA 80) mg sc at Week 26 followed by ADA 40 mg sc eow from Week 27 through Week 51.

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 randomized to the placebo treatment group received 2 injections of placebo at Baseline (Day 1), and then starting at Week 1, received a single injection of placebo eow through Week 25.

Arm title	Adalimumab EOW

Arm description:

Period A: ADA 40 mg sc eow for 25 weeks starting 1 week after initial loading dose of 80 mg. Period B: Placebo at Week 26 followed by ADA 40 mg sc eow from Week 27 through Week 51.

Arm type	Experimental
Investigational medicinal product name	adalimumab
Investigational medicinal product code	
Other name	Humira 40 mg solution for injection in pre-filled syringe
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects randomized to the adalimumab treatment group received 80 mg sc adalimumab at Baseline (Day 1) administered as 2 injections of 40 mg adalimumab, and then starting at Week 1 received a single injection of adalimumab 40 mg sc eow through Week 25.

Number of subjects in period 1	Placebo	Adalimumab EOW
Started	108	109
Completed	94	94
Not completed	14	15
Consent withdrawn by subject	3	4
Adverse event, non-fatal	3	5
Not Specified	3	-
Required Alternative/Prohibited Therapy	-	1
Lost to follow-up	3	3
Lack of efficacy	2	1
Protocol deviation	-	1

Period 2

Period 2 title	Period B
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Period A: Placebo subcutaneous every other week (sc eow) for 25 weeks. Period B: ADA 80 mg sc at Week 26 followed by ADA 40 mg sc eow from Week 27 through Week 51.

Arm type	Placebo
Investigational medicinal product name	adalimumab
Investigational medicinal product code	
Other name	Humira 40 mg solution for injection in pre-filled syringe
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

At the Week 26 visit subjects from the placebo group were to receive 80 mg sc adalimumab administered as 2 injections of 40 mg adalimumab. Starting at the Week 27 study visit, all subjects were to receive 1 injection of 40 mg sc of adalimumab eow through Week 51. No medication was to be dispensed or injected at the Week 52 study visit.

Arm title	Adalimumab EOW

Arm description:

Period A: ADA 40 mg sc eow for 25 weeks starting 1 week after initial loading dose of 80 mg. Period B: Placebo at Week 26 followed by ADA 40 mg sc eow from Week 27 through Week 51.

Arm type	Experimental

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:

At Week 26. subjects from the adalimumab group were to receive 2 injections of matching placebo.

Investigational medicinal product name	adalimumab
Investigational medicinal product code	
Other name	Humira 40 mg solution for injection in pre-filled syringe
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Starting at the Week 27 study visit, all subjects were to receive 1 injection of 40 mg sc of adalimumab eow through Week 51. No medication was to be dispensed or injected at the Week 52 study visit.

Number of subjects in period 2	Placebo	Adalimumab EOW
Started	94	94
Completed	81	87
Not completed	13	7
Consent withdrawn by subject	1	1
Not Specified	4	-
Required Alternative/Prohibited Therapy	-	2
Lost to follow-up	2	-
Lack of efficacy	6	4

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Period A: Placebo subcutaneous every other week (sc eow) for 25 weeks. Period B: Adalimumab (ADA 80) mg sc at Week 26 followed by ADA 40 mg sc eow from Week 27 through Week 51.	
Reporting group title	Adalimumab EOW
Reporting group description:	
Period A: ADA 40 mg sc eow for 25 weeks starting 1 week after initial loading dose of 80 mg. Period B: Placebo at Week 26 followed by ADA 40 mg sc eow from Week 27 through Week 51.	

Reporting group values	Placebo	Adalimumab EOW	Total
Number of subjects	108	109	217
Age, Customized Units: participants			
< 40 years	34	30	64
40 to ≤ 64 years	65	70	135
≥ 65 years	9	9	18
Age Continuous Units: years			
arithmetic mean	46.16	47.21	
standard deviation	± 12.134	± 11.858	-
Gender, Male/Female Units: Participants			
Female	21	13	34
Male	87	96	183

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Period A: Placebo subcutaneous every other week (sc eow) for 25 weeks. Period B: Adalimumab (ADA 80) mg sc at Week 26 followed by ADA 40 mg sc eow from Week 27 through Week 51.	
Reporting group title	Adalimumab EOW
Reporting group description:	
Period A: ADA 40 mg sc eow for 25 weeks starting 1 week after initial loading dose of 80 mg. Period B: Placebo at Week 26 followed by ADA 40 mg sc eow from Week 27 through Week 51.	
Reporting group title	Placebo
Reporting group description:	
Period A: Placebo subcutaneous every other week (sc eow) for 25 weeks. Period B: ADA 80 mg sc at Week 26 followed by ADA 40 mg sc eow from Week 27 through Week 51.	
Reporting group title	Adalimumab EOW
Reporting group description:	
Period A: ADA 40 mg sc eow for 25 weeks starting 1 week after initial loading dose of 80 mg. Period B: Placebo at Week 26 followed by ADA 40 mg sc eow from Week 27 through Week 51.	

Primary: Percentage of Participants Achieving a Total Fingernail Modified Nail Psoriasis Severity Index (mNAPSI) 75 Response at Week 26

End point title	Percentage of Participants Achieving a Total Fingernail Modified Nail Psoriasis Severity Index (mNAPSI) 75 Response at Week 26
End point description:	
Each fingernail was assessed for psoriasis with mNAPSI, and the scores of all 10 fingernails were combined. Investigators assessed each nail abnormality for each of a participant's nails by grading 3 features or groups of features (pitting, onycholysis and oil-drop dyschromia, and crumbling) and noting the presence or absence of 4 features (leukonychia, splinter hemorrhages, hyperkeratosis, and red spots in the lunula). The range of possible scores was 0 to 130, with a score of 0 indicating absence of nail psoriasis and a score of 130 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement. The mNAPSI 75 response is defined as at least 75% reduction from baseline in mNAPSI.	
End point type	Primary
End point timeframe:	
Week 26	

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percentage of participants				
number (not applicable)	3.4	46.6		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: For US regulatory purposes, ranked first secondary endpoint.	
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [1]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	43.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.8
upper limit	53.6

Notes:

[1] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Primary: For United States (US) Regulatory Purposes: Percentage of Participants With a Physician's Global Assessment of Fingernails (PGA-F) of "Clear" or "Minimal" at Week 26

End point title	For United States (US) Regulatory Purposes: Percentage of Participants With a Physician's Global Assessment of Fingernails (PGA-F) of "Clear" or "Minimal" at Week 26
End point description: The PGA-F is a 5-point scale used to assess fingernails separately for nail bed signs and nail matrix signs of disease. A global score of between 0 indicating clear, and 4 indicating severe, was separately assigned for nail bed involvement and nail matrix involvement. A participant's overall global score was the worse of the nail bed and nail matrix score. Data presents the percentage of participants with a PGA-F overall global score that met the definition of “clear” (0) or “minimal" (1) with at least a 2-grade improvement relative to Baseline at Week 26.	
End point type	Primary
End point timeframe: Week 26	

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percentage of participants				
number (not applicable)	6.9	48.9		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Ranked sixth secondary endpoint. For US regulatory purposes, this was the primary endpoint.	

Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [2]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	42
Confidence interval	
level	95 %
sides	2-sided
lower limit	30.8
upper limit	53.2

Notes:

[2] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Percent Change From Baseline in Total Fingernail Nail Psoriasis Severity Index (NAPSI) Score at Week 26

End point title	Percent Change From Baseline in Total Fingernail Nail Psoriasis Severity Index (NAPSI) Score at Week 26

End point description:

Each fingernail was assessed for nail matrix psoriasis and nail bed psoriasis with NAPSI and the scores of all 10 fingernails were combined. The range of possible scores was 0 to 80, with a score of 0 indicating absence of nail psoriasis and 80 indicating most severe nail psoriasis. A decrease in NAPSI score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percent change				
least squares mean (standard error)	-11.5 (± 3.19)	-56.2 (± 3.12)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Ranked first secondary endpoint. For US regulatory purposes, ranked second secondary endpoint.

Comparison groups	Placebo v Adalimumab EOW

Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [3]
Method	ANCOVA
Parameter estimate	LS Mean
Point estimate	-44.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-53.5
upper limit	-36

Notes:

[3] - P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Percentage of Participants Achieving Total Fingernail mNAPSI Score of 0 at Week 26

End point title	Percentage of Participants Achieving Total Fingernail mNAPSI Score of 0 at Week 26

End point description:

Each fingernail was assessed for psoriasis with mNAPSI, and the scores of all 10 fingernails were combined. The range of possible scores was 0 to 130, with a score of 0 indicating absence of nail psoriasis and a score of 130 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.

End point type	Secondary

End point timeframe:

Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percentage of participants				
number (not applicable)	0	6.6		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Ranked second secondary endpoint. For US regulatory purposes, ranked third secondary endpoint.

Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008 [4]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	6.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.8
upper limit	11.3

Notes:

[4] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Percent Change From Baseline in Nail Psoriasis Pain Numeric Rating Scale (NRS) at Week 26

End point title	Percent Change From Baseline in Nail Psoriasis Pain Numeric Rating Scale (NRS) at Week 26

End point description:

An NRS was used to capture a participant's self-reporting of her/his worst fingernail pain and average fingernail pain due to fingernail psoriasis. The participant rated the severity of fingernail pain over the past 7 days on a scale from 0 indicating no pain, to 10 indicating severe pain. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percent change				
least squares mean (standard error)	-1.1 (± 0.24)	-3.7 (± 0.23)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Ranked third secondary endpoint. For US regulatory purposes, ranked fourth secondary endpoint.

Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [5]
Method	ANCOVA
Parameter estimate	LS Mean Percent Change
Point estimate	-2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.3
upper limit	-2

Notes:

[5] - P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Change From Baseline in Nail Psoriasis Physical Functioning Severity Score at Week 26

End point title	Change From Baseline in Nail Psoriasis Physical Functioning Severity Score at Week 26

End point description:

Participants were asked to rate the impact of their fingernail psoriasis on their ability to perform physical tasks (eg, typing, housework, buttoning a shirt or blouse, picking up coins from a table, tying shoes, yard work, etc.) over the past 7 days on a scale of 0 indicating no impact on ability to perform physical tasks, to 10 indicating severe impact on ability to perform physical tasks. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: units on a scale				
least squares mean (standard error)	-0.8 (± 0.24)	-3.7 (± 0.25)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Ranked fourth secondary endpoint. For US regulatory purposes, ranked fifth secondary endpoint.

Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [6]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	-2.2

Notes:

[6] - P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Percentage of Participants With at Least 50% Improvement in the Scalp Component of the Brigham Scalp Nail Inverse Palmo-Plantar Psoriasis Index (B-

SNIPI) at Week 26	
End point title	Percentage of Participants With at Least 50% Improvement in the Scalp Component of the Brigham Scalp Nail Inverse Palmo-Plantar Psoriasis Index (B-SNIPI) at Week 26
End point description:	
The range of possible scores was 0 to 20 for scalp psoriasis, with a score of 0 indicating absence of psoriasis. A decrease in B-SNIPI score indicates improvement. Data presents the percentage of participants achieving 50% improvement in the scalp component of the B-SNIPI among participants with Baseline scalp score of ≥ 6.	
End point type	Secondary
End point timeframe:	
Baseline, Week 26	

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	18		
Units: percentage of participants				
number (not applicable)	0.4	58.3		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Ranked fifth secondary endpoint. For US regulatory purposes, ranked sixth secondary endpoint.	
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [7]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	57.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.8
upper limit	82

Notes:

[7] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Percentage of Participants Achieving "Clear" or "Minimal" in Nail Bed Component of the PGA-F at Week 26	
End point title	Percentage of Participants Achieving "Clear" or "Minimal" in Nail Bed Component of the PGA-F at Week 26
End point description:	
The PGA-F is a 5-point scale used to assess fingernails separately for nail bed signs and nail matrix signs of disease. A global score of between 0 indicating clear, and 4 indicating severe, was separately	

assigned for nail bed involvement and nail matrix involvement. A participant's overall global score was the worse of the nail bed and nail matrix score. Data presents the percentage of participants with a nail bed component of the PGA-F that met definition of "clear" (0) or "minimal" (1) among those with a Baseline nail bed component of "moderate" or "worse."

End point type	Secondary

End point timeframe:

Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101	98		
Units: percentage of participants				
number (not applicable)	8.2	51.4		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [8]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	43.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	31.3
upper limit	55.2

Notes:

[8] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Percentage of Participants Achieving "Clear" or "Minimal" in Nail Matrix Component of the PGA-F At Week 26

End point title	Percentage of Participants Achieving "Clear" or "Minimal" in Nail Matrix Component of the PGA-F At Week 26

End point description:

The PGA-F is a 5-point scale used to assess fingernails separately for nail bed signs and nail matrix signs of disease. A global score of between 0 indicating clear, and 4 indicating severe, was separately assigned for nail bed involvement and nail matrix involvement. A participant's overall global score was the worse of the nail bed and nail matrix score. Data presents the percentage of participants with a nail matrix component of the PGA-F that met definition of "clear" (0) or "minimal" (1) among those with a Baseline nail matrix component of "moderate" or "worse."

End point type	Secondary

End point timeframe:

Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	99	102		
Units: percentage of participants				
number (not applicable)	8.5	53.3		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	201
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [9]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	44.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.2
upper limit	56.5

Notes:

[9] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Percentage of Participants Achieving Target Fingernail mNAPSI Score of 0 at Week 26

End point title	Percentage of Participants Achieving Target Fingernail mNAPSI Score of 0 at Week 26

End point description:

The target fingernail was assessed for psoriasis with mNAPSI. The range of possible scores was 0 to 13, with a score of 0 indicating absence of nail psoriasis and a score of 13 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.

End point type	Secondary

End point timeframe:

Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percentage of participants				
number (not applicable)	1.3	19.9		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [10]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	18.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.6
upper limit	26.6

Notes:

[10] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Percentage of Participants Achieving Target Fingernail mNAPSI Score of ≤ 2 at Week 26

End point title	Percentage of Participants Achieving Target Fingernail mNAPSI Score of ≤ 2 at Week 26

End point description:

The target fingernail was assessed for psoriasis with mNAPSI. The range of possible scores was 0 to 13, with a score of 0 indicating absence of nail psoriasis and a score of 13 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.

End point type	Secondary

End point timeframe:

Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percentage of participants				
number (not applicable)	7.3	43.3		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [11]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	36
Confidence interval	
level	95 %
sides	2-sided
lower limit	25
upper limit	46.9

Notes:

[11] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Percentage of Participants Achieving Total Fingernail mNAPSI Score of ≤ 2 at Week 26

End point title	Percentage of Participants Achieving Total Fingernail mNAPSI Score of ≤ 2 at Week 26

End point description:

Each fingernail was assessed for psoriasis with mNAPSI, and the scores of all 10 fingernails were combined. The range of possible scores was 0 to 130, with a score of 0 indicating absence of nail psoriasis and a score of 130 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.

End point type	Secondary

End point timeframe:

Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percentage of participants				
number (not applicable)	0.2	13.4		

Statistical analyses

Statistical analysis title	STATISTICAL_ANALYSIS_TITLE
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [12]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	13.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.5
upper limit	20

Notes:

[12] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Change From Baseline in Target Fingernail mNAPSI Score at Week 26

End point title	Change From Baseline in Target Fingernail mNAPSI Score at Week 26

End point description:

The target fingernail was assessed for psoriasis with mNAPSI. The range of possible scores was 0 to 13, with a score of 0 indicating absence of nail psoriasis and a score of 13 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: units on a scale				
least squares mean (standard error)	-2.1 (± 0.27)	-5.7 (± 0.27)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [13]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-3.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.3
upper limit	-2.8

Notes:

[13] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Percent Change From Baseline in Target Fingernail mNAPSI Score at Week 26

End point title	Percent Change From Baseline in Target Fingernail mNAPSI Score at Week 26

End point description:

The target fingernail was assessed for psoriasis with mNAPSI. The range of possible scores was 0 to 13, with a score of 0 indicating absence of nail psoriasis and a score of 13 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percent change				
least squares mean (standard error)	-23 (± 2.92)	-61.9 (± 2.91)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [14]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-38.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.9
upper limit	-30.8

Notes:

[14] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Change From Baseline in Total Fingernail mNAPSI Score at Week 26

End point title	Change From Baseline in Total Fingernail mNAPSI Score at Week 26

End point description:

Each fingernail was assessed for psoriasis with mNAPSI, and the scores of all 10 fingernails were combined. The range of possible scores was 0 to 130, with a score of 0 indicating absence of nail psoriasis and a score of 130 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: units on a scale				
least squares mean (standard error)	-7.5 (± 1.78)	-36.1 (± 1.8)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [15]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-28.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.5
upper limit	-23.7

Notes:

[15] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Percent Change From Baseline in Total Fingernail mNAPSI Score at Week 26

End point title	Percent Change From Baseline in Total Fingernail mNAPSI Score at Week 26

End point description:

Each fingernail was assessed for psoriasis with mNAPSI, and the scores of all 10 fingernails were combined. The range of possible scores was 0 to 130, with a score of 0 indicating absence of nail psoriasis and a score of 130 indicating the most severe nail psoriasis. A decrease in mNAPSI score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percent change				
least squares mean (standard error)	-13.2 (± 3.06)	-63.3 (± 3.02)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [16]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-50.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-58.3
upper limit	-41.9

Notes:

[16] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Percentage of Participants Achieving Total Fingernail NAPSI Score of 0 at Week 26

End point title	Percentage of Participants Achieving Total Fingernail NAPSI Score of 0 at Week 26

End point description:

Each fingernail was assessed for nail matrix psoriasis and nail bed psoriasis with NAPSI and the scores of all 10 fingernails were combined. The range of possible scores was 0 to 80, with a score of 0 indicating absence of nail psoriasis and 80 indicating most severe nail psoriasis. A decrease in NAPSI score indicates improvement.

End point type	Secondary

End point timeframe:

Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percentage of participants				
number (not applicable)	0	7.5		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004 [17]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	7.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.4
upper limit	12.4

Notes:

[17] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Percentage of Participants Achieving Target Fingernail NAPSI Score of 0 at Week 26

End point title	Percentage of Participants Achieving Target Fingernail NAPSI Score of 0 at Week 26

End point description:

The target fingernail was assessed for nail matrix psoriasis and nail bed psoriasis with NAPSI. The range of possible scores was 0 to 8, with a score of 0 indicating absence of nail psoriasis and 8 indicating most severe nail psoriasis. A decrease in NAPSI score indicates improvement.

End point type	Secondary

End point timeframe:

Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percentage of participants				
number (not applicable)	2.4	20.8		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [18]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	18.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.1
upper limit	26.8

Notes:

[18] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Change from Baseline in Target Fingernail NAPSI Score at Week 26

End point title	Change from Baseline in Target Fingernail NAPSI Score at Week 26

End point description:

The target fingernail was assessed for nail matrix psoriasis and nail bed psoriasis with NAPSI. The range of possible scores was 0 to 8, with a score of 0 indicating absence of nail psoriasis and 8 indicating most severe nail psoriasis. A decrease in NAPSI score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: units on a scale				
least squares mean (standard error)	-1.1 (± 0.21)	-3.6 (± 0.21)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [19]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-2.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	-1.9

Notes:

[19] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Percent Change from Baseline in Target Fingernail NAPSI Score at Week 26

End point title	Percent Change from Baseline in Target Fingernail NAPSI Score at Week 26

End point description:

The target fingernail was assessed for nail matrix psoriasis and nail bed psoriasis with NAPSI. The range of possible scores was 0 to 8, with a score of 0 indicating absence of nail psoriasis and 8 indicating most severe nail psoriasis. A decrease in NAPSI score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percent change				
least squares mean (standard error)	-14.4 (± 3.5)	-54.6 (± 3.47)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [20]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-40.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-50
upper limit	-30.4

Notes:

[20] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Change from Baseline in Total Fingernail NAPSI Score at Week 26

End point title	Change from Baseline in Total Fingernail NAPSI Score at Week 26

End point description:

Each fingernail was assessed for nail matrix psoriasis and nail bed psoriasis with NAPSI and the scores of all 10 fingernails were combined. The range of possible scores was 0 to 80, with a score of 0 indicating absence of nail psoriasis and 80 indicating most severe nail psoriasis. A decrease in NAPSI score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: units on a scale				
least squares mean (standard error)	-6.7 (± 1.51)	-26.2 (± 1.47)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [21]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-19.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.6
upper limit	-15.3

Notes:

[21] - Across all strata, P values were calculated from ANCOVA with stratum, Baseline value, and treatment in the model.

Secondary: Change From Baseline in Psoriasis Area Severity Index (PASI) Score at

Week 26

End point title	Change From Baseline in Psoriasis Area Severity Index (PASI) Score at Week 26

End point description:

PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (plaque thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The score ranges from 0 to 72, with 0 indicating no psoriasis and 72 indicating very severe psoriasis. A decrease in PASI score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: units on a scale				
least squares mean (standard error)	-0.9 (± 0.7)	-9 (± 0.7)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [22]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	-6.1

Notes:

[22] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Percent Change From Baseline in PASI Score at Week 26

End point title	Percent Change From Baseline in PASI Score at Week 26

End point description:

PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (plaque thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The score ranges from 0 to 72, with 0 indicating no psoriasis and 72 indicating very severe psoriasis. A decrease in PASI score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percent change				
least squares mean (standard error)	2.4 (± 5.77)	-68.7 (± 5.7)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [23]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-71.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-87.3
upper limit	-55

Notes:

[23] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Percentage of Participants Achieving PASI 75/50/90/100 Responses at Week 26

End point title	Percentage of Participants Achieving PASI 75/50/90/100 Responses at Week 26

End point description:

PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (plaque thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The score ranges from 0 to 72, with 0 indicating no psoriasis and 72 indicating very severe psoriasis. PASI-75, 50, 90, and 100 responses are the percentage of participants with a Baseline PASI score ≥ 5 who achieved at least a 75%, 50%, 90%, or 100% reduction (improvement), respectively, from Baseline in PASI score at Week 26. A 100% reduction was considered complete clearance of psoriasis. Data presents the percentage of participants achieving PASI 75/50/90/100 responses at Week 26 among participants with a Baseline PASI score ≥ 5.

End point type	Secondary

End point timeframe:

Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	95	97		
Units: percentage of participants				
number (not applicable)				
PASI 75	13.8	64.8		
PASI 50	25.3	77.8		
PASI 90	7.1	48		
PASI 100	2.9	29.3		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: PASI 75	
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [24]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	51.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	38.6
upper limit	63.5

Notes:

[24] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: PASI 50	
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [25]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	52.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	39.9
upper limit	65

Notes:

[25] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: PASI 90	
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [26]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	40.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	29
upper limit	52.9

Notes:

[26] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: PASI 100	
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [27]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	26.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.8
upper limit	36.9

Notes:

[27] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Percentage of Participants Achieving Physician's Global Assessment of Skin Psoriasis (PGA-S) "Clear" or "Minimal" at Week 26

End point title	Percentage of Participants Achieving Physician's Global Assessment of Skin Psoriasis (PGA-S) "Clear" or "Minimal" at Week 26

End point description:

The PGA-S is a 6-point scale used to measure the severity of skin disease at the time of the qualified investigator's evaluation of the participant. The degree of overall lesion severity was assessed, with 0

indicating cleared and 5 indicating severe. A decrease in PGA-S score indicates improvement. Data present the percentage of participants achieving a PGA-S of "clear" (0) or "minimal" (1) with at least a 2-grade improvement relative to Baseline at Week 26.

End point type	Secondary

End point timeframe:

Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percentage of participants				
number (not applicable)	11.2	63.4		

Statistical analyses

Statistical analysis title	STATISTICAL_ANALYSIS_TITLE
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [28]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	52.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	40.8
upper limit	63.7

Notes:

[28] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Percentage of Participants Achieving PGA-S of "Clear" at Week 26

End point title	Percentage of Participants Achieving PGA-S of "Clear" at Week 26

End point description:

The PGA-S is a 6-point scale used to measure the severity of skin disease at the time of the qualified investigator's evaluation of the participant. The degree of overall lesion severity was assessed, with 0 indicating cleared and 5 indicating severe. A decrease in PGA-S score indicates improvement. Data present the percentage of participants achieving a PGA-S of "clear" (0) with at least a 2-grade improvement relative to Baseline at Week 26.

End point type	Secondary

End point timeframe:

Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percentage of participants				
number (not applicable)	4	28.8		

Statistical analyses

Statistical analysis title	STATISTICAL_ANALYSIS_TITLE
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [29]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	24.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.3
upper limit	34.3

Notes:

[29] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Percentage of Participants Achieving 50% Improvement in the Inverse Psoriasis Component of the B-SNIPI at Week 26

End point title	Percentage of Participants Achieving 50% Improvement in the Inverse Psoriasis Component of the B-SNIPI at Week 26

End point description:

The range of possible B-SNIPI scores was 0 to 20 for inverse psoriasis, with a score of 0 indicating absence of psoriasis and a score of 20 indicating most severe psoriasis. A decrease in B-SNIPI score indicates improvement. Data presents the percentage of participants achieving 50% improvement in the inverse component of the B-SNIPI among participants with a Baseline inverse psoriasis score of ≥ 6.

End point type	Secondary

End point timeframe:

Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	12		
Units: percentage of participants				
number (not applicable)	0.5	90.8		

Statistical analyses

Statistical analysis title	STATISTICAL_ANALYSIS_TITLE
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [30]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	90.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	72.5
upper limit	108.3

Notes:

[30] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Change From Baseline in Total Body Surface Area (BSA) at Week 26

End point title	Change From Baseline in Total Body Surface Area (BSA) at Week 26

End point description:

BSA affected by psoriasis was measured by the physician selecting the participant's right or left hand as the measuring device. For purposes of clinical estimation, the total surface of the palm plus 5 digits was to be assumed to be approximately equivalent to 1% BSA. Measurement of the total area of involvement by the physician was aided by imagining if scattered plaques were moved so that they were next to each other and then estimated the total area involved. A decrease in BSA affected by psoriasis indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percentage of affected BSA				
least squares mean (standard error)	0.4 (± 1)	-10.7 (± 1)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [31]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-11.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.9
upper limit	-8.4

Notes:

[31] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Percent Change From Baseline in Total BSA at Week 26

End point title	Percent Change From Baseline in Total BSA at Week 26

End point description:

BSA affected by psoriasis was measured by the physician selecting the participant's right or left hand as the measuring device. For purposes of clinical estimation, the total surface of the palm plus 5 digits was to be assumed to be approximately equivalent to 1% BSA. Measurement of the total area of involvement by the physician was aided by imagining if scattered plaques were moved so that they were next to each other and then estimated the total area involved. A decrease in BSA affected by psoriasis indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percent change				
least squares mean (standard error)	12.8 (± 6.08)	-67.8 (± 6.01)		

Statistical analyses

Statistical analysis title	STATISTICAL_ANALYSIS_TITLE
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [32]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-80.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-97.9
upper limit	-63.3

Notes:

[32] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Percent Change From Baseline in Nail Psoriasis Pain NRS at Week 26

End point title	Percent Change From Baseline in Nail Psoriasis Pain NRS at Week 26

End point description:

An NRS was used to capture a participant's self-reporting of her/his worst fingernail pain and average fingernail pain due to fingernail psoriasis. The participant rated the severity of fingernail pain over the past 7 days on a scale from 0 indicating no pain, to 10 indicating severe pain. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	103		
Units: percent change				
least squares mean (standard error)	-18 (± 4.8)	-68.9 (± 4.7)		

Statistical analyses

Statistical analysis title	STATISTICAL_ANALYSIS_TITLE
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	206
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [33]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-50.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-64
upper limit	-37.8

Notes:

[33] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Percent Change From Baseline in Nail Psoriasis Physical Functioning Severity Score at Week 26

End point title	Percent Change From Baseline in Nail Psoriasis Physical Functioning Severity Score at Week 26

End point description:

Participants were asked to rate the impact of their fingernail psoriasis on their ability to perform physical tasks (eg, typing, housework, buttoning a shirt or blouse, picking up coins from a table, tying shoes, yard work, etc.) over the past 7 days on a scale of 0 indicating no impact on ability to perform physical tasks, to 10 indicating severe impact on ability to perform physical tasks. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	105	104		
Units: percent change				
least squares mean (standard error)	-9.9 (± 5.51)	-67.6 (± 5.63)		

Statistical analyses

Statistical analysis title	STATISTICAL_ANALYSIS_TITLE
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [34]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-57.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-73.1
upper limit	-42.4

Notes:

[34] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Change From Baseline in Nail Assessment in Psoriasis and Psoriatic Arthritis Quality of Life (NAPPA QoL) at Week 26

End point title	Change From Baseline in Nail Assessment in Psoriasis and Psoriatic Arthritis Quality of Life (NAPPA QoL) at Week 26

End point description:

Participants rated specific impacts of fingernail psoriasis on various aspects of their QoL over the past 7 days on a 5-point scale, with 0 indicating not at all, and 4 indicating very impactful. A participant's overall global score was the mean of all items and could range from 0 to 4, with 0 indicating no impact and 4 indicating most impact. A decrease in NAPPA QoL score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: units on a scale				
least squares mean (standard error)	-0.4 (± 0.07)	-1.3 (± 0.07)		

Statistical analyses

Statistical analysis title	STATISTICAL_ANALYSIS_TITLE
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [35]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	-0.7

Notes:

[35] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Percent Change From Baseline in Nail Assessment in NAPPA QoL at Week 26

End point title	Percent Change From Baseline in Nail Assessment in NAPPA QoL at Week 26

End point description:	
Participants rated specific impacts of fingernail psoriasis on various aspects of their QoL over the past 7 days on a 5-point scale, with 0 indicating not at all, and 4 indicating very impactful. A participant's overall global score was the mean of all items and could range from 0 to 4, with 0 indicating no impact and 4 indicating most impact. A decrease in NAPPA QoL score indicates improvement.	
End point type	Secondary
End point timeframe:	
Baseline, Week 26	

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: percent change				
least squares mean (standard error)	-11.7 (± 2.24)	-39.5 (± 2.23)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [36]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-27.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.9
upper limit	-21.6

Notes:

[36] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Change From Baseline in Dermatology Life Quality Index (DLQI) Score at Week 26

End point title	Change From Baseline in Dermatology Life Quality Index (DLQI) Score at Week 26
End point description:	
Participants assessed symptoms and impacts of dermatologic diseases on their QoL over the past 7 days, with 0 indicating not at all, and 3 indicating very much. The range of possible DLQI scores was 0 to 30, with a score of 0 indicating no effect at all on a participant's life and a score of 30 indicating extremely large effect on participant's life. A decrease in DLQI score indicates improvement.	
End point type	Secondary
End point timeframe:	
Baseline, Week 26	

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	93	94		
Units: units on a scale				
least squares mean (standard error)	-1.9 (± 0.6)	-8 (± 0.6)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [37]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-6.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.8
upper limit	-4.5

Notes:

[37] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Percentage of Participants Achieving DLQI of 0 and 0/1 at Week 26

End point title	Percentage of Participants Achieving DLQI of 0 and 0/1 at Week 26

End point description:

Participants assessed symptoms and impacts of dermatologic diseases on their QoL over the past 7 days, with 0 indicating not at all, and 3 indicating very much. The range of possible DLQI scores was 0 to 30, with a score of 0 indicating no effect at all on a participant's life and a score of 30 indicating extremely large effect on participant's life. A decrease in DLQI score indicates improvement. Data presents the percentage of participants with a score of 0 (no effect) or 1 (little effect) at Week 26.

End point type	Secondary

End point timeframe:

Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	93	94		
Units: percentage of participants				
number (not applicable)				
DLQI = 0	2.5	18.2		
DLQI = 0/1	3.7	30.8		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: DLQI = 0	
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [38]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	15.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.1
upper limit	24.3

Notes:

[38] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: DLQI = 0/1	
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [39]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	27.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.7
upper limit	37.4

Notes:

[39] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Change From Baseline in Work Productivity and Activity Impairment Nail Psoriasis (WPAI:NPSO) at Week 26

End point title	Change From Baseline in Work Productivity and Activity Impairment Nail Psoriasis (WPAI:NPSO) at Week 26

End point description:

The WPAI: NPSO assessed impact of fingernail psoriasis on work productivity and non-work activity limitation. Participants were asked during the past 7 days, how many hours did you miss from work because of problems associated with your fingernail psoriasis (absenteeism), during the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study (presenteeism), how much did your fingernail psoriasis affect your productivity while you were working (overall work impairment), and much did your fingernail psoriasis affect your ability to do your regular daily activities, other than work at a job (activity impairment). Answers were rated on an 11-point scale, with 0 indicating "fingernail psoriasis had no effect on this" and 10 indicating "fingernail psoriasis completely prevented me from this." A decrease in the WPAI:NPSO score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: units on a scale				
least squares mean (standard error)				
Absenteeism; n=65, 74	-1 (± 0.73)	-0.3 (± 0.65)		
Presenteeism; n=70, 77	-3.4 (± 2.08)	-20.7 (± 2.06)		
Overall Work impairment; n=65, 74	-6.2 (± 2.2)	-21.3 (± 2.05)		
Activity impairment; n=106, 108	-1.8 (± 2.09)	-23.1 (± 2.18)		

Statistical analyses

Statistical analysis title	STATISTICAL_ANALYSIS_TITLE

Statistical analysis description:

Absenteeism

Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.416 [40]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	0.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	2.5

Notes:

[40] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Presenteeism	
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [41]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-17.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.9
upper limit	-11.6

Notes:

[41] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Overall work impairment	
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [42]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-15.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21
upper limit	-9.3

Notes:

[42] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Activity impairment	
Comparison groups	Placebo v Adalimumab EOW

Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [43]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-21.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.3
upper limit	-15.4

Notes:

[43] - Across all strata, P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Change From Baseline in EuroQol-5 Dimensions-5 Levels (EQ-5D-5L) Health State Assessment at Week 26

End point title	Change From Baseline in EuroQol-5 Dimensions-5 Levels (EQ-5D-5L) Health State Assessment at Week 26

End point description:

The EQ-5D-5L descriptive system comprises 5 dimensions of health (mobility, self -care, usual activities, pain/discomfort, and anxiety/depression) to describe the subject's current health state. Each dimension comprises 5 levels with corresponding numeric scores, where 1 indicates no problems, and 5 indicates extreme problems. A unique EQ-5D-5L health state is defined by combining the numeric level scores for each of the 5 dimensions and the total score is normalized from –0.594 to 1.000, with higher scores representing a better health state. An increase in the EQ-5D-5L total score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	107	109		
Units: units on a scale				
least squares mean (standard error)	0 (± 0.01)	0.1 (± 0.01)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	216
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [44]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	0.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	0.2

Notes:

[44] - P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Change From Baseline in EQ-5D Visual analogue Scale (VAS) at Week 26

End point title	Change From Baseline in EQ-5D Visual analogue Scale (VAS) at Week 26

End point description:

The EQ-5D VAS records the participant's self-rated health status on a vertical graduated scale from 0 to 100, with 0 indicating the worst imaginable health state and 100 indicating the best imaginable health state. An increase in EQ-5D-5L VAS score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	107	109		
Units: units on a scale				
least squares mean (standard error)	-0.1 (± 1.53)	5.5 (± 1.53)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	216
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.012 [45]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	5.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.2
upper limit	9.8

Notes:

[45] - P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Change From Baseline in Hospital Anxiety Depression Scale (HADS) at Week 26

End point title	Change From Baseline in Hospital Anxiety Depression Scale (HADS) at Week 26

End point description:

Participants rated their anxiety and depression over the past 7 days at Week 26. The range of possible scores was 0 to 21, with a score of 0 indicating absence of
anxiety and depression and 21 indicating the most severe anxiety and depression. A decrease in HADS score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108	109		
Units: units on a scale				
least squares mean (standard error)				
HADS anxiety score; n=106, 109	-0.1 (± 0.33)	-1.1 (± 0.33)		
HADS depression score; n=106, 108	0 (± 0.33)	-1.4 (± 0.32)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

HADS anxiety score

Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.025 [46]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	-0.1

Notes:

[46] - P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

HADS depression score

Comparison groups	Placebo v Adalimumab EOW

Number of subjects included in analysis	217
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005 [47]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	-0.4

Notes:

[47] - P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Secondary: Percentage of Participants With a New Diagnosis of Psoriatic Arthritis (PsA) During the Study

End point title	Percentage of Participants With a New Diagnosis of Psoriatic Arthritis (PsA) During the Study

End point description:

The percentage of participants with a new diagnosis of PsA (ie, with an adverse event of PsA) during the study, among participants without PsA at Baseline.

End point type	Secondary

End point timeframe:

up to Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	76	79		
Units: percentage of participants				
number (not applicable)	0	2		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	155
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.164 [48]
Method	Chi-squared
Parameter estimate	Difference in percentage
Point estimate	2.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	6

Notes:

[48] - Cochran-Mantel-Haenszel test adjusted for strata. If zero frequency occurred, strata were dropped and p-value was calculated based on chi-square test (or adjusted chi-square test based on Campbell [2007]).

Secondary: Change From Baseline in Nail Psoriasis Quality of Life (Nail PsQoL) Score at Week 26

End point title	Change From Baseline in Nail Psoriasis Quality of Life (Nail PsQoL) Score at Week 26

End point description:

Participants were asked how their fingernail psoriasis impacted their overall quality of life over the past 7 days on an 11-point scale, with 0 indicating no impact, and 10 indicating severe impact. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 26

End point values	Placebo	Adalimumab EOW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	107	109		
Units: units on a scale				
least squares mean (standard error)	-0.6 (± 0.23)	-3.3 (± 0.23)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Adalimumab EOW
Number of subjects included in analysis	216
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [49]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	-2.1

Notes:

[49] - P values were calculated from ANCOVA with treatment center stratum, Baseline value, and treatment in the model.

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Adverse events were collected from Baseline through Week 52 +70 day follow up phone call; serious adverse events were collected from Screening through Week 52 + 70 day follow up call.	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	18.0
Reporting groups	
Reporting group title	Placebo (Period A)
Reporting group description:	
Placebo sc eow for 25 weeks. Period B: ADA 80 mg sc at Week 26 followed by ADA 40 mg sc eow from Week 27 through Week 51.	
Reporting group title	Adalimumab EOW (Period A)
Reporting group description:	
ADA 40 mg sc eow for 25 weeks starting 1 week after initial loading dose of 80 mg.	
Reporting group title	Placebo/Adalimumab EOW (Period B)
Reporting group description:	
Following Period A (placebo sc eow for 25 weeks), ADA 80 mg sc at Week 26 followed by ADA 40 mg sc eow from Week 27 through Week 51.	
Reporting group title	Adalimumab EOW/Adalimumab EOW (Period B)
Reporting group description:	
Following Period A (ADA 40 mg sc eow for 25 weeks starting 1 week after initial loading dose of 80 mg), placebo at Week 26 followed by ADA 40 mg sc eow from Week 27 through Week 51.	

Serious adverse events	Placebo (Period A)	Adalimumab EOW (Period A)	Placebo/Adalimumab EOW (Period B)
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 108 (4.63%)	8 / 109 (7.34%)	3 / 94 (3.19%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Vascular disorders			
HYPERTENSIVE CRISIS			
subjects affected / exposed	0 / 108 (0.00%)	1 / 109 (0.92%)	0 / 94 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
ANAPHYLACTIC REACTION			
subjects affected / exposed	0 / 108 (0.00%)	1 / 109 (0.92%)	0 / 94 (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
Reproductive system and breast			

disorders			
PROSTATITIS			
subjects affected / exposed	0 / 108 (0.00%)	1 / 109 (0.92%)	0 / 94 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
BRONCHOSPASM			
subjects affected / exposed	1 / 108 (0.93%)	0 / 109 (0.00%)	0 / 94 (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
Psychiatric disorders			
MAJOR DEPRESSION			
subjects affected / exposed	0 / 108 (0.00%)	1 / 109 (0.92%)	0 / 94 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUICIDAL IDEATION			
subjects affected / exposed	0 / 108 (0.00%)	1 / 109 (0.92%)	0 / 94 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ARTHROPOD STING			
subjects affected / exposed	0 / 108 (0.00%)	1 / 109 (0.92%)	0 / 94 (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
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 108 (0.93%)	0 / 109 (0.00%)	0 / 94 (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
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 108 (0.00%)	1 / 109 (0.92%)	0 / 94 (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
MYOCARDIAL INFARCTION			

subjects affected / exposed	0 / 108 (0.00%)	0 / 109 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CAROTID ARTERY STENOSIS			
subjects affected / exposed	1 / 108 (0.93%)	0 / 109 (0.00%)	0 / 94 (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
SEIZURE			
subjects affected / exposed	0 / 108 (0.00%)	0 / 109 (0.00%)	0 / 94 (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
Gastrointestinal disorders			
DIVERTICULAR PERFORATION			
subjects affected / exposed	0 / 108 (0.00%)	1 / 109 (0.92%)	0 / 94 (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
Skin and subcutaneous tissue disorders			
PSORIASIS			
subjects affected / exposed	1 / 108 (0.93%)	0 / 109 (0.00%)	0 / 94 (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
Renal and urinary disorders			
BLADDER SPHINCTER ATONY			
subjects affected / exposed	0 / 108 (0.00%)	0 / 109 (0.00%)	0 / 94 (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
STRESS URINARY INCONTINENCE			
subjects affected / exposed	0 / 108 (0.00%)	0 / 109 (0.00%)	0 / 94 (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			
TENOSYNOVITIS			

subjects affected / exposed	0 / 108 (0.00%)	0 / 109 (0.00%)	0 / 94 (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			
BRONCHITIS			
subjects affected / exposed	0 / 108 (0.00%)	1 / 109 (0.92%)	0 / 94 (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
DIVERTICULITIS			
subjects affected / exposed	0 / 108 (0.00%)	1 / 109 (0.92%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOCARDITIS			
subjects affected / exposed	0 / 108 (0.00%)	1 / 109 (0.92%)	0 / 94 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ERYSIPELAS			
subjects affected / exposed	0 / 108 (0.00%)	1 / 109 (0.92%)	0 / 94 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFLUENZA			
subjects affected / exposed	0 / 108 (0.00%)	0 / 109 (0.00%)	0 / 94 (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
LUNG INFECTION			
subjects affected / exposed	0 / 108 (0.00%)	0 / 109 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	2 / 108 (1.85%)	0 / 109 (0.00%)	0 / 94 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Adalimumab		

	EOW/Adalimumab EOW (Period B)		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 94 (3.19%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Vascular disorders			
HYPERTENSIVE CRISIS			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
ANAPHYLACTIC REACTION			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
PROSTATITIS			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
BRONCHOSPASM			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
MAJOR DEPRESSION			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
SUICIDAL IDEATION			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural			

complications			
ARTHROPOD STING			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
CAROTID ARTERY STENOSIS			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
SEIZURE			
subjects affected / exposed	1 / 94 (1.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
DIVERTICULAR PERFORATION			
subjects affected / exposed	0 / 94 (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 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
BLADDER SPHINCTER ATONY			
subjects affected / exposed	1 / 94 (1.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
STRESS URINARY INCONTINENCE			
subjects affected / exposed	1 / 94 (1.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
TENOSYNOVITIS			
subjects affected / exposed	1 / 94 (1.06%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
DIVERTICULITIS			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ENDOCARDITIS			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ERYSIPELAS			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

INFLUENZA			
subjects affected / exposed	1 / 94 (1.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
LUNG INFECTION			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
PNEUMONIA			
subjects affected / exposed	1 / 94 (1.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Placebo (Period A)	Adalimumab EOW (Period A)	Placebo/Adalimumab EOW (Period B)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	43 / 108 (39.81%)	45 / 109 (41.28%)	28 / 94 (29.79%)
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 108 (1.85%)	0 / 109 (0.00%)	0 / 94 (0.00%)
occurrences (all)	2	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 108 (1.85%)	0 / 109 (0.00%)	1 / 94 (1.06%)
occurrences (all)	2	0	1
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	3 / 108 (2.78%)	0 / 109 (0.00%)	1 / 94 (1.06%)
occurrences (all)	3	0	1
Injury, poisoning and procedural complications			
LACERATION			
subjects affected / exposed	0 / 108 (0.00%)	3 / 109 (2.75%)	0 / 94 (0.00%)
occurrences (all)	0	3	0
Vascular disorders			

HYPERTENSION			
subjects affected / exposed	2 / 108 (1.85%)	4 / 109 (3.67%)	0 / 94 (0.00%)
occurrences (all)	2	5	0
Nervous system disorders			
HEADACHE			
subjects affected / exposed	0 / 108 (0.00%)	6 / 109 (5.50%)	2 / 94 (2.13%)
occurrences (all)	0	6	3
General disorders and administration site conditions			
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 108 (0.00%)	1 / 109 (0.92%)	2 / 94 (2.13%)
occurrences (all)	0	1	2
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 108 (0.00%)	3 / 109 (2.75%)	0 / 94 (0.00%)
occurrences (all)	0	3	0
INJECTION SITE PAIN			
subjects affected / exposed	2 / 108 (1.85%)	1 / 109 (0.92%)	2 / 94 (2.13%)
occurrences (all)	2	1	2
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	2 / 108 (1.85%)	3 / 109 (2.75%)	1 / 94 (1.06%)
occurrences (all)	2	3	1
TOOTHACHE			
subjects affected / exposed	0 / 108 (0.00%)	0 / 109 (0.00%)	0 / 94 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	3 / 108 (2.78%)	2 / 109 (1.83%)	1 / 94 (1.06%)
occurrences (all)	3	2	1
OROPHARYNGEAL PAIN			
subjects affected / exposed	3 / 108 (2.78%)	2 / 109 (1.83%)	1 / 94 (1.06%)
occurrences (all)	3	2	1
Skin and subcutaneous tissue disorders			
DERMATITIS CONTACT			
subjects affected / exposed	0 / 108 (0.00%)	3 / 109 (2.75%)	0 / 94 (0.00%)
occurrences (all)	0	3	0
PSORIASIS			

subjects affected / exposed	6 / 108 (5.56%)	1 / 109 (0.92%)	4 / 94 (4.26%)
occurrences (all)	7	1	4
Psychiatric disorders			
DEPRESSION			
subjects affected / exposed	1 / 108 (0.93%)	1 / 109 (0.92%)	0 / 94 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	4 / 108 (3.70%)	5 / 109 (4.59%)	0 / 94 (0.00%)
occurrences (all)	5	5	0
BACK PAIN			
subjects affected / exposed	4 / 108 (3.70%)	2 / 109 (1.83%)	1 / 94 (1.06%)
occurrences (all)	4	2	1
PSORIATIC ARTHROPATHY			
subjects affected / exposed	1 / 108 (0.93%)	2 / 109 (1.83%)	0 / 94 (0.00%)
occurrences (all)	1	2	0
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 108 (0.00%)	2 / 109 (1.83%)	3 / 94 (3.19%)
occurrences (all)	0	2	3
GASTROENTERITIS			
subjects affected / exposed	1 / 108 (0.93%)	4 / 109 (3.67%)	3 / 94 (3.19%)
occurrences (all)	1	4	3
NASOPHARYNGITIS			
subjects affected / exposed	10 / 108 (9.26%)	6 / 109 (5.50%)	9 / 94 (9.57%)
occurrences (all)	11	9	10
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	9 / 108 (8.33%)	9 / 109 (8.26%)	6 / 94 (6.38%)
occurrences (all)	11	11	7
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 108 (0.93%)	1 / 109 (0.92%)	2 / 94 (2.13%)
occurrences (all)	2	1	3
Metabolism and nutrition disorders			
HYPERLIPIDAEMIA			
subjects affected / exposed	0 / 108 (0.00%)	3 / 109 (2.75%)	0 / 94 (0.00%)
occurrences (all)	0	3	0

Non-serious adverse events	Adalimumab EOW/Adalimumab EOW (Period B)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	34 / 94 (36.17%)		
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 94 (2.13%)		
occurrences (all)	2		
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 94 (2.13%)		
occurrences (all)	2		
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	1 / 94 (1.06%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
LACERATION			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences (all)	0		
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	1 / 94 (1.06%)		
occurrences (all)	1		
Nervous system disorders			
HEADACHE			
subjects affected / exposed	1 / 94 (1.06%)		
occurrences (all)	1		
General disorders and administration site conditions			
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences (all)	0		
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences (all)	0		
INJECTION SITE PAIN			

subjects affected / exposed	1 / 94 (1.06%)		
occurrences (all)	1		
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	2 / 94 (2.13%)		
occurrences (all)	2		
TOOTHACHE			
subjects affected / exposed	3 / 94 (3.19%)		
occurrences (all)	3		
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	0 / 94 (0.00%)		
occurrences (all)	0		
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 94 (1.06%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
DERMATITIS CONTACT			
subjects affected / exposed	1 / 94 (1.06%)		
occurrences (all)	1		
PSORIASIS			
subjects affected / exposed	1 / 94 (1.06%)		
occurrences (all)	1		
Psychiatric disorders			
DEPRESSION			
subjects affected / exposed	3 / 94 (3.19%)		
occurrences (all)	3		
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 94 (1.06%)		
occurrences (all)	1		
BACK PAIN			
subjects affected / exposed	2 / 94 (2.13%)		
occurrences (all)	2		
PSORIATIC ARTHROPATHY			

subjects affected / exposed	2 / 94 (2.13%)		
occurrences (all)	2		
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	2 / 94 (2.13%)		
occurrences (all)	2		
GASTROENTERITIS			
subjects affected / exposed	2 / 94 (2.13%)		
occurrences (all)	2		
NASOPHARYNGITIS			
subjects affected / exposed	12 / 94 (12.77%)		
occurrences (all)	14		
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	4 / 94 (4.26%)		
occurrences (all)	4		
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 94 (1.06%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
HYPERLIPIDAEMIA			
subjects affected / exposed	1 / 94 (1.06%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 January 2014	Key changes included in Amendment 1 included revision of the PGA-F from a 6-point scale to a 5-point scale to reduce the potential overlap among the levels of severity of fingernail Ps and addition of the B-SNIPI. Besides clarifying minor inconsistencies and making minor editorial changes within the protocol, the purpose of Amendment 1 was to incorporate changes to protocol section text and tables.

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.

Due to study design, a high percentage of participants randomized to the placebo arm early escaped from Period A and thus participated for a shorter duration than did participants in the active treatment arm.

Notes: