Clinical trial results:
A prospective, single-centre, feasibility study evaluating the prevalence of diagnostic clinical imaging features of subclinical enthesitis in patients with moderate to severe plaque psoriasis and the response to skin directed treatment with Ustekinumab

Summary

EudraCT number	2012-002640-25
Trial protocol	GB
Global end of trial date	26 October 2016

Results information

Result version number	v1 (current)
This version publication date	18 December 2019
First version publication date	18 December 2019

Trial information

Trial identification

Sponsor protocol code	RR12/10234

Additional study identifiers

ISRCTN number	ISRCTN18043449
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Sponsor Number: RR12/10234

Notes:

Sponsors

Sponsor organisation name	University of Leeds
Sponsor organisation address	Clarendon way, Leeds, United Kingdom, LS2 9JT
Public contact	Academic Unit of MSK Disease, University of Leeds Institute of Molecular Medicine (Section of Musculoskeletal Disease), 44 07817407699, D.G.McGonagle@leeds.ac.uk
Scientific contact	Academic Unit of MSK Disease, University of Leeds Institute of Molecular Medicine (Section of Musculoskeletal Disease), 44 07817407699, D.G.McGonagle@leeds.ac.uk

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	02 February 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 October 2015
Global end of trial reached?	Yes
Global end of trial date	26 October 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Do the imaging features of subclinical enthesopathy (the earliest change seen in psoriatic arthritis), as measured by peripheral joint ultrasound (USS) and whole body MRI, in patients with moderate-to-severe psoriasis (PASI>10), change when treated for 24 weeks with ustekinumab (at standard dose) for their psoriatic skin disease?

Protection of trial subjects:

All trial subjects were protected as Per University of Leeds Indemnity. All members of the trial team are appropriately GCP trained and have experience within their research fields.

Background therapy:

All treatments being taken (prescribed or otherwise) taken by participants on entry to the study or at any time during the study, in addition to the investigational product are regarded as concomitant treatments and will be documented.
Concomitant medications should be kept to a minimum during the study. However, if these are considered necessary for the participants' welfare, and are unlikely to interfere with the investigational products, they may be permitted at the discretion of the investigator and recorded.

Permitted concomitant medications
- Topical psoriasis therapies, including:

o Emollients
o Vitamin D analogues
o Topical corticosteroids
o Coal tar preparations
o Dithranol
o Tazarotene
o Eosin

- Analgesic medications, including paracetamol, codeine, tramadol and morphine. PRN use of NSAID medications is permitted as long as it is NOT excess of two standard doses (e.g. ibuprofen 400mg) per week.

Evidence for comparator:

This is a single arm, open label feasibility study, with no comparator.

Actual start date of recruitment	01 January 2013
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	United Kingdom: 23

Worldwide total number of subjects	23
EEA total number of subjects	23

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)	22
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment opened 01.01.2013. Patients were recruited between the dates of 19.07.2013 and 20.10.2014.

Pre-assignment

Screening details:

Males & females, aged >18, with plaque psoriasis, naive to systemic or biologic therapy, with certain characteristics:
Moderate/severe severity chronic plaque psoriasis (PASI >10) with disease duration of >=12 months.
No symptoms of PsA (no EMS>15mins, no joint swelling, no CASPAR or Moll & Wright criteria)
Presence of subclinical USS enthesitis

Period 1

Period 1 title	Main trial
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	ustekinumab

Arm description:

Patients administered ustekinumab

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

Dosage and administration details:

45mg solution for Injection in pre filled syringe

Number of subjects in period 1	ustekinumab
Started	23
Completed	23

Period 2

Period 2 title	Week 52 extension (optional)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	ustekinumab

Arm description:

Patients administered ustekinumab

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

Dosage and administration details:

45mg solution for Injection in pre filled syringe

Number of subjects in period 2[1]	ustekinumab
Started	20
Completed	20

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: this phase was optional and not all patients opted to continue to this extended period of follow-up

Baseline characteristics

Reporting groups

Reporting group title	Main trial

Reporting group description: -

Reporting group values	Main trial	Total	
Number of subjects	23	23	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	22	22	
From 65-84 years	1	1	
85 years and over	0	0	
Age continuous Units: years			
median	45		
inter-quartile range (Q1-Q3)	33 to 55	-	
Gender categorical Units: Subjects			
Female	11	11	
Male	12	12	

Subject analysis sets

Subject analysis set title	Full analysis set
Subject analysis set type	Full analysis

Subject analysis set description:

This set includes all patients who were recruited to receive Ustekinumab, irrespective of subsequent treatment status

Reporting group values	Full analysis set		
Number of subjects	23		
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			

Adults (18-64 years) From 65-84 years 85 years and over	22 1		
Age continuous Units: years median inter-quartile range (Q1-Q3)	 45 33 to 55		
Gender categorical Units: Subjects			
Female Male	11 12		

End points

End points reporting groups

Reporting group title	ustekinumab
Reporting group description:	
Patients administered ustekinumab	
Reporting group title	ustekinumab
Reporting group description:	
Patients administered ustekinumab	
Subject analysis set title	Full analysis set
Subject analysis set type	Full analysis
Subject analysis set description:	
This set includes all patients who were recruited to receive Ustekinumab, irrespective of subsequent treatment status	

Primary: US Total enthesitis score 24

End point title	US Total enthesitis score 24
End point description:	
End point type	Primary
End point timeframe:	
Week 24	

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
arithmetic mean (standard deviation)	14.8 (± 10.6)	14.8 (± 10.6)		

Statistical analyses

Statistical analysis title	US Total enthesitis score 24
Comparison groups	ustekinumab v Full analysis set
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	= 0.034
Method	Paired Student's t-test
Parameter estimate	Change from baseline
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.7
upper limit	-0.2

Variability estimate	Standard deviation
Dispersion value	6.3

Notes:

[1] - Exploratory superiority

Primary: US Inflammation enthesitis score 24

End point title	US Inflammation enthesitis score 24

End point description:

End point type	Primary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
arithmetic mean (standard deviation)	5.7 (± 5.3)	5.7 (± 5.3)		

Statistical analyses

Statistical analysis title	US Inflammation enthesitis score 24
Comparison groups	ustekinumab v Full analysis set
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other[2]
P-value	< 0.001
Method	Paired Student's t-test
Parameter estimate	Change from baseline
Point estimate	-4.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	-2.1
Variability estimate	Standard deviation
Dispersion value	4.9

Notes:

[2] - Exploratory superiority

Primary: US Chronic enthesitis score 24

End point title	US Chronic enthesitis score 24

End point description:

End point type	Primary
End point timeframe: Week 24	

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
arithmetic mean (standard deviation)	9.1 (± 6.5)	9.1 (± 6.5)		

Statistical analyses

Statistical analysis title	US Chronic enthesitis score 24
Comparison groups	ustekinumab v Full analysis set
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other[3]
P-value	= 0.082
Method	Paired Student's t-test
Parameter estimate	Change from baseline
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	2.7
Variability estimate	Standard deviation
Dispersion value	3.3

Notes:

[3] - Exploratory analysis of within-group change from baseline for single arm study

Secondary: US Total enthesitis score 12

End point title	US Total enthesitis score 12
End point description:	

End point type	Secondary
End point timeframe: Week 12	

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
arithmetic mean (standard deviation)	13.8 (± 9.1)	13.8 (± 9.1)		

Statistical analyses

Statistical analysis title	US Total enthesitis score 12
Comparison groups	ustekinumab v Full analysis set
Number of subjects included in analysis	46
Analysis specification	Post-hoc
Analysis type	other[4]
P-value	= 0.001
Method	Paired Student's t-test
Parameter estimate	Change from baseline
Point estimate	-4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6
upper limit	-1.9
Variability estimate	Standard deviation
Dispersion value	4.7

Notes:

[4] - Exploratory superiority

Secondary: US Total enthesitis score 52

End point title	US Total enthesitis score 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[5]		
Units: AU				
arithmetic mean (standard deviation)	13.6 (± 9.9)	13.6 (± 9.9)		

Notes:

[5] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

Statistical analysis title	US Total enthesitis score 52
Comparison groups	ustekinumab v Full analysis set
Number of subjects included in analysis	40
Analysis specification	Post-hoc
Analysis type	other[6]
P-value	= 0.047
Method	Paired Student's t-test
Parameter estimate	Change from baseline
Point estimate	-4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.8
upper limit	-0.1
Variability estimate	Standard deviation
Dispersion value	8.3

Notes:

[6] - Exploratory superiority

Secondary: US Inflammation enthesitis score 12

End point title	US Inflammation enthesitis score 12

End point description:

End point type	Secondary

End point timeframe:

Week 12

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
arithmetic mean (standard deviation)	6.8 (± 4.9)	6.8 (± 4.9)		

Statistical analyses

Statistical analysis title	US Inflammation enthesitis score 24
Comparison groups	ustekinumab v Full analysis set

Number of subjects included in analysis	46
Analysis specification	Post-hoc
Analysis type	other[7]
P-value	= 0.001
Method	Paired Student's t-test
Parameter estimate	Change from baseline
Point estimate	-3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	-1.5
Variability estimate	Standard deviation
Dispersion value	3.8

Notes:

[7] - Exploratory superiority

Secondary: US Inflammation enthesitis score 52

End point title	US Inflammation enthesitis score 52
End point description:	
End point type	Secondary
End point timeframe:	
Week 52	

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[8]		
Units: AU				
arithmetic mean (standard deviation)	4.8 (± 4.6)	4.8 (± 4.6)		

Notes:

[8] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

Statistical analysis title	US Inflammation enthesitis score 52
Comparison groups	ustekinumab v Full analysis set
Number of subjects included in analysis	40
Analysis specification	Post-hoc
Analysis type	other[9]
P-value	= 0.001
Method	Paired Student's t-test
Parameter estimate	Change from baseline
Point estimate	-4.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	-2.3
Variability estimate	Standard deviation
Dispersion value	5.2

Notes:

[9] - Exploratory superiority

Secondary: US Chronic enthesitis score 12

End point title	US Chronic enthesitis score 12

End point description:

End point type	Secondary

End point timeframe:

Week 12

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
arithmetic mean (standard deviation)	7.0 (± 5.7)	7.0 (± 5.7)		

Statistical analyses

Statistical analysis title	US Chronic enthesitis score 12
Comparison groups	ustekinumab v Full analysis set
Number of subjects included in analysis	46
Analysis specification	Post-hoc
Analysis type	other[10]
P-value	= 0.137
Method	Paired Student's t-test
Parameter estimate	Change from baseline
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	0.3
Variability estimate	Standard deviation
Dispersion value	2.6

Notes:

[10] - Exploratory superiority

Secondary: US Chronic enthesitis score 52

End point title	US Chronic enthesitis score 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[11]		
Units: AU				
arithmetic mean (standard deviation)	8.6 (± 7.0)	8.6 (± 7.0)		

Notes:

[11] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

Statistical analysis title	US Chronic enthesitis score 52
Comparison groups	ustekinumab v Full analysis set
Number of subjects included in analysis	40
Analysis specification	Post-hoc
Analysis type	other[12]
P-value	= 0.512
Method	Paired Student's t-test
Parameter estimate	Change from baseline
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	3.1
Variability estimate	Standard deviation
Dispersion value	5

Notes:

[12] - Exploratory superiority

Secondary: MRI BMO Peripheral Skeleton 24

End point title	MRI BMO Peripheral Skeleton 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
arithmetic mean (standard deviation)	2.30 (± 2.40)	2.30 (± 2.40)		

Statistical analyses

No statistical analyses for this end point

Secondary: MRI BMO Peripheral Skeleton 52

End point title	MRI BMO Peripheral Skeleton 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[13]		
Units: AU				
arithmetic mean (standard deviation)	2.55 (± 2.80)	2.55 (± 2.80)		

Notes:

[13] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: MRI Bursitis Peripheral Skeleton 24

End point title	MRI Bursitis Peripheral Skeleton 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
arithmetic mean (standard deviation)	2.26 (± 1.71)	2.26 (± 1.71)		

Statistical analyses

No statistical analyses for this end point

Secondary: MRI Bursitis Peripheral Skeleton 52

End point title	MRI Bursitis Peripheral Skeleton 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[14]		
Units: AU				
arithmetic mean (standard deviation)	2.20 (± 1.82)	2.20 (± 1.82)		

Notes:

[14] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: MRI Synovitis Peripheral Skeleton 24

End point title	MRI Synovitis Peripheral Skeleton 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
arithmetic mean (standard deviation)	3.39 (± 1.88)	3.39 (± 1.88)		

Statistical analyses

No statistical analyses for this end point

Secondary: MRI Synovitis Peripheral Skeleton 52

End point title	MRI Synovitis Peripheral Skeleton 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[15]		
Units: AU				
arithmetic mean (standard deviation)	3.30 (± 1.92)	3.30 (± 1.92)		

Notes:

[15] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: MRI Tenosynovitis/Enthesitis Peripheral Skeleton 24

End point title	MRI Tenosynovitis/Enthesitis Peripheral Skeleton 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
arithmetic mean (standard deviation)	0.17 (± 0.58)	0.17 (± 0.58)		

Statistical analyses

No statistical analyses for this end point

Secondary: MRI Tenosynovitis/Enthesitis Peripheral Skeleton 52

End point title	MRI Tenosynovitis/Enthesitis Peripheral Skeleton 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[16]		
Units: AU				
arithmetic mean (standard deviation)	0.25 (± 0.64)	0.25 (± 0.64)		

Notes:

[16] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: MRI BMO Spine 24

End point title	MRI BMO Spine 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
arithmetic mean (standard deviation)	1.91 (± 2.64)	1.91 (± 2.64)		

Statistical analyses

No statistical analyses for this end point

Secondary: MRI BMO Spine 52

End point title	MRI BMO Spine 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[17]		
Units: AU				
arithmetic mean (standard deviation)	1.55 (± 2.01)	1.55 (± 2.01)		

Notes:

[17] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: MRI Fatty Infiltration Spine 24

End point title	MRI Fatty Infiltration Spine 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
arithmetic mean (standard deviation)	0.39 (± 1.12)	0.39 (± 1.12)		

Statistical analyses

No statistical analyses for this end point

Secondary: MRI Fatty Infiltration Spine 52

End point title	MRI Fatty Infiltration Spine 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[18]		
Units: AU				
arithmetic mean (standard deviation)	0.40 (± 1.89)	0.40 (± 1.89)		

Notes:

[18] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: MRI BMO Sacroiliac Joints 24

End point title	MRI BMO Sacroiliac Joints 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
arithmetic mean (standard deviation)	0.30 (± 0.88)	0.30 (± 0.88)		

Statistical analyses

No statistical analyses for this end point

Secondary: MRI BMO Sacroiliac Joints 52

End point title	MRI BMO Sacroiliac Joints 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[19]		
Units: AU				
arithmetic mean (standard deviation)	0.10 (± 0.31)	0.10 (± 0.31)		

Notes:

[19] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: MRI Erosions Sacroiliac Joints 24

End point title	MRI Erosions Sacroiliac Joints 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
arithmetic mean (standard deviation)	0.09 (± 0.42)	0.09 (± 0.42)		

Statistical analyses

No statistical analyses for this end point

Secondary: MRI Erosions Sacroiliac Joints 52

End point title	MRI Erosions Sacroiliac Joints 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[20]		
Units: AU				
arithmetic mean (standard deviation)	0.09 (± 0.42)	0.09 (± 0.42)		

Notes:

[20] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: PASI 12

End point title	PASI 12

End point description:

End point type	Secondary

End point timeframe:

Week 12

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	2.3 (0.9 to 3.9)	2.3 (0.9 to 3.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: PASI 24

End point title	PASI 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	0.6 (0.0 to 2.5)	0.6 (0.0 to 2.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: PASI 52

End point title	PASI 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[21]		
Units: AU				
median (inter-quartile range (Q1-Q3))	0.1 (0.0 to 2.9)	0.1 (0.0 to 2.9)		

Notes:

[21] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: BSA 12

End point title	BSA 12

End point description:

End point type	Secondary

End point timeframe:

Week 12

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: percent				
median (inter-quartile range (Q1-Q3))	5.0 (1.0 to 10.0)	5.0 (1.0 to 10.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: BSA 24

End point title	BSA 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: percent				
median (inter-quartile range (Q1-Q3))	1.0 (0.0 to 3.0)	1.0 (0.0 to 3.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: BSA 52

End point title	BSA 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[22]		
Units: percent				
median (inter-quartile range (Q1-Q3))	0.5 (0.0 to 2.75)	0.5 (0.0 to 2.75)		

Notes:

[22] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: mNAPSI 12

End point title	mNAPSI 12

End point description:

End point type	Secondary

End point timeframe:

Week 12

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	3.0 (0.0 to 16.0)	3.0 (0.0 to 16.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: mNAPSI 24

End point title	mNAPSI 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	0.0 (0.0 to 9.0)	0.0 (0.0 to 9.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: mNAPSI 52

End point title	mNAPSI 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[23]		
Units: AU				
median (inter-quartile range (Q1-Q3))	3.5 (0.0 to 6.75)	3.5 (0.0 to 6.75)		

Notes:

[23] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: DLQI 12

End point title	DLQI 12

End point description:

End point type	Secondary

End point timeframe:

Week 12

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	1.0 (0.0 to 6.0)	1.0 (0.0 to 6.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: DLQI 24

End point title	DLQI 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: DLQI 52

End point title	DLQI 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	19[24]	19[25]		
Units: AU				
median (inter-quartile range (Q1-Q3))	0.0 (0.0 to 3.0)	0.0 (0.0 to 3.0)		

Notes:

[24] - One patient did not complete the DLQI at week 52

[25] - Three patients in the full analysis set did not complete the optional week 52 assessment, 1 missing

Statistical analyses

No statistical analyses for this end point

Secondary: HB 24

End point title	HB 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	146 (140 to 154)	146 (140 to 154)		

Statistical analyses

No statistical analyses for this end point

Secondary: HB 52

End point title	HB 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[26]		
Units: AU				
median (inter-quartile range (Q1-Q3))	146 (139.5 to 155.25)	146 (139.5 to 155.25)		

Notes:

[26] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: MCV 24

End point title	MCV 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	93.0 (90.0 to 98.0)	93.0 (90.0 to 98.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: MCV 52

End point title	MCV 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[27]		
Units: AU				
median (inter-quartile range (Q1-Q3))	94.0 (90.25 to 99.5)	94.0 (90.25 to 99.5)		

Notes:

[27] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: Platelets 24

End point title	Platelets 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	308.0 (249.0 to 342.0)	308.0 (249.0 to 342.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Platelets 52

End point title	Platelets 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[28]		
Units: AU				
median (inter-quartile range (Q1-Q3))	289.0 (242.0 to 355.5)	289.0 (242.0 to 355.5)		

Notes:

[28] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: WCC 24

End point title	WCC 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	6.77 (5.64 to 7.49)	6.77 (5.64 to 7.49)		

Statistical analyses

No statistical analyses for this end point

Secondary: WCC 52

End point title	WCC 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[29]		
Units: AU				
median (inter-quartile range (Q1-Q3))	6.70 (6.10 to 7.76)	6.70 (6.10 to 7.76)		

Notes:

[29] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: Neutrophils 24

End point title	Neutrophils 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	3.78 (3.28 to 4.54)	3.78 (3.28 to 4.54)		

Statistical analyses

No statistical analyses for this end point

Secondary: Neutrophils 52

End point title	Neutrophils 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[30]		
Units: AU				
median (inter-quartile range (Q1-Q3))	3.65 (3.38 to 4.56)	3.65 (3.38 to 4.56)		

Notes:

[30] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: Lymphocytes 24

End point title	Lymphocytes 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	1.99 (1.53 to 2.56)	1.99 (1.53 to 2.56)		

Statistical analyses

No statistical analyses for this end point

Secondary: Lymphocytes 52

End point title	Lymphocytes 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[31]		
Units: AU				
median (inter-quartile range (Q1-Q3))	1.75 (1.40 to 2.41)	1.75 (1.40 to 2.41)		

Notes:

[31] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: CRP 24

End point title	CRP 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: CRP 52

End point title	CRP 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[32]		
Units: AU				
median (inter-quartile range (Q1-Q3))	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)		

Notes:

[32] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: PV 24

End point title	PV 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	1.64 (1.57 to 1.68)	1.64 (1.57 to 1.68)		

Statistical analyses

No statistical analyses for this end point

Secondary: PV 52

End point title	PV 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[33]		
Units: AU				
median (inter-quartile range (Q1-Q3))	1.66 (1.60 to 1.71)	1.66 (1.60 to 1.71)		

Notes:

[33] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: Urea 24

End point title	Urea 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	5.40 (4.40 to 6.30)	5.40 (4.40 to 6.30)		

Statistical analyses

No statistical analyses for this end point

Secondary: Urea 52

End point title	Urea 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[34]		
Units: AU				
median (inter-quartile range (Q1-Q3))	4.95 (4.43 to 5.55)	4.95 (4.43 to 5.55)		

Notes:

[34] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine 24

End point title	Creatinine 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	67.00 (55.00 to 77.00)	67.00 (55.00 to 77.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine 52

End point title	Creatinine 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[35]		
Units: AU				
median (inter-quartile range (Q1-Q3))	72.50 (57.75 to 81.25)	72.50 (57.75 to 81.25)		

Notes:

[35] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: Na 24

End point title	Na 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	140.00 (140.00 to 141.00)	140.00 (140.00 to 141.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: Na 52

End point title	Na 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[36]		
Units: AU				
median (inter-quartile range (Q1-Q3))	140.00 (138.25 to 141.00)	140.00 (138.25 to 141.00)		

Notes:

[36] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: K 24

End point title	K 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	4.40 (4.10 to 4.60)	4.40 (4.10 to 4.60)		

Statistical analyses

No statistical analyses for this end point

Secondary: K 52

End point title	K 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[37]		
Units: AU				
median (inter-quartile range (Q1-Q3))	4.35 (4.10 to 4.60)	4.35 (4.10 to 4.60)		

Notes:

[37] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: ALT 24

End point title	ALT 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	26.00 (23.00 to 36.00)	26.00 (23.00 to 36.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: ALT 52

End point title	ALT 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[38]		
Units: AU				
median (inter-quartile range (Q1-Q3))	27.00 (18.50 to 39.25)	27.00 (18.50 to 39.25)		

Notes:

[38] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin 24

End point title	Bilirubin 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	8.00 (5.00 to 12.00)	8.00 (5.00 to 12.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin 52

End point title	Bilirubin 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[39]		
Units: AU				
median (inter-quartile range (Q1-Q3))	11.00 (8.00 to 15.00)	11.00 (8.00 to 15.00)		

Notes:

[39] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: ALP 24

End point title	ALP 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	170.00 (140.00 to 208.00)	170.00 (140.00 to 208.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: ALP 52

End point title	ALP 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[40]		
Units: AU				
median (inter-quartile range (Q1-Q3))	173.00 (127.25 to 207.25)	173.00 (127.25 to 207.25)		

Notes:

[40] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: Albumin 24

End point title	Albumin 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	45.00 (44.00 to 47.00)	45.00 (44.00 to 47.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: Albumin 52

End point title	Albumin 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[41]		
Units: AU				
median (inter-quartile range (Q1-Q3))	45.00 (42.25 to 45.75)	45.00 (42.25 to 45.75)		

Notes:

[41] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: ANA 24

End point title	ANA 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: Positive	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: ANA 52

End point title	ANA 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[42]		
Units: Positive	0	0		

Notes:

[42] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: HDL cholesterol 24

End point title	HDL cholesterol 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	1.50 (1.20 to 1.75)	1.50 (1.20 to 1.75)		

Statistical analyses

No statistical analyses for this end point

Secondary: HDL cholesterol 52

End point title	HDL cholesterol 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[43]		
Units: AU				
median (inter-quartile range (Q1-Q3))	1.35 (1.20 to 1.80)	1.35 (1.20 to 1.80)		

Notes:

[43] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: LDL cholesterol 24

End point title	LDL cholesterol 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	2.60 (2.45 to 3.70)	2.60 (2.45 to 3.70)		

Statistical analyses

No statistical analyses for this end point

Secondary: LDL cholesterol 52

End point title	LDL cholesterol 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[44]		
Units: AU				
median (inter-quartile range (Q1-Q3))	2.65 (2.30 to 4.00)	2.65 (2.30 to 4.00)		

Notes:

[44] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: Triglycerides 24

End point title	Triglycerides 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	1.50 (0.90 to 2.15)	1.50 (0.90 to 2.15)		

Statistical analyses

No statistical analyses for this end point

Secondary: Triglycerides 52

End point title	Triglycerides 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[45]		
Units: AU				
median (inter-quartile range (Q1-Q3))	1.30 (0.85 to 2.10)	1.30 (0.85 to 2.10)		

Notes:

[45] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Secondary: Glucose 24

End point title	Glucose 24

End point description:

End point type	Secondary

End point timeframe:

Week 24

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	23	23		
Units: AU				
median (inter-quartile range (Q1-Q3))	4.80 (4.50 to 5.65)	4.80 (4.50 to 5.65)		

Statistical analyses

No statistical analyses for this end point

Secondary: Glucose 52

End point title	Glucose 52

End point description:

End point type	Secondary

End point timeframe:

Week 52

End point values	ustekinumab	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	20	20[46]		
Units: AU				
median (inter-quartile range (Q1-Q3))	5.00 (4.70 to 6.65)	5.00 (4.70 to 6.65)		

Notes:

[46] - Three patients in the full analysis set did not complete the optional week 52 assessment

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs and SAEs will be collected from the signing of the informed consent form to 30 days after the end of a patient's participation in the trial (the last study visit at week 24 or early discontinuation visit).

Assessment type	Systematic

Dictionary used

Dictionary name	NA
Dictionary version	NA

Reporting groups

Reporting group title	ustekinumab

Reporting group description:

Patients administered ustekinumab

Serious adverse events	ustekinumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 23 (8.70%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Fracture	Additional description: One patient was involved in a road traffic accident while riding her scooter just before her week 16 visit and sustained a severe fracture of her left femur. She underwent surgical pinning and was hospitalised for several weeks. Not attributed to IMP		
subjects affected / exposed	1 / 23 (4.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abscess intestinal	Additional description: Another patient developed an abdominal pericolic gutter abscess at week 37 of treatment (last investigational dose was week 16). Required hospitalisation + IV antibiotics for 7 days, but recovered. Possibly UST related but treatment continued.		
subjects affected / exposed	1 / 23 (4.35%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	ustekinumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 23 (86.96%)		
Investigations			
Anaemia	Additional description: One patient was found to be anaemic at week 16 and was referred back to GP for further investigation (OGD, colonoscopy and CT); they later received an iron infusion.		
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Soft tissue injury	Additional description: One patient sustained accidental trauma to the left shoulder at the gymnasium around week 2 and chose to wear a sling for a couple of weeks but did not seek medical advice. He was symptom free and had a full ROM at his next review at week 4		
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Fracture	Additional description: At week 16 one patient had a possible fracture in their 2nd toe on their right foot, but this required no surgery or treatment.		
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	4 / 23 (17.39%)		
occurrences (all)	4		
Gastrointestinal disorders			
Gastroenteritis	Additional description: Developed around week 22. This was self-limiting and did not require any treatment other than rest and oral hydration.		
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Dyspepsia	Additional description: At the 52 week visit (during the optional extension phase during which UST was administered under standard of care) one patient reported dyspepsia four days after the last dose of UST; however, a prick test was negative.		
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea	Additional description: At the 52 week visit (during the optional extension phase during which UST was administered under standard of care) one patient reported shortness of breath four days after the last dose of UST; however, a prick test was negative.		
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Acne	Additional description: One patient developed facial acne for which a topical retinoid/benzoyl peroxide product was prescribed		

subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Folliculitis	Additional description: One patient developed small areas of folliculitis on the abdominal wall, away from the injection site, which resolved without treatment		
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Rash	Additional description: At the week 24 visit, one patient was found to have erythema and bran-like scale in both gaiter areas, more right side than left, more lateral than medial, with ill-defined margins.		
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Renal and urinary disorders			
Hypertension	Additional description: At week 16 it was reported that another patient had developed hypertension and had seen a cardiologist for tests. They were given a heart monitor and a renal ultrasound was arranged. Their candesartan dose was increased.		
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Infections and infestations			
Upper respiratory tract infection	Additional description: Five patients developed an upper respiratory tract infection (1 at week 4, 4 around week 12) for which they consulted with their General Practitioner, for which two received a short course of oral antibiotics.		
subjects affected / exposed	5 / 23 (21.74%)		
occurrences (all)	5		
Tooth abscess	Additional description: One patient reported a tooth abscess at week 4		
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Nail infection	Additional description: One patient had a fungal nail infection on their great toe at the 52 week visit (during the optional extension phase during which UST was administered under standard of care).		
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 October 2013	Protocol amended to v2.0. Addition of a control group to the trial consisting of psoriasis patients attending for NBUVB phototherapy. TO undergo US on peripheral joints and whole body MRI. Associated documentation also added to the trial including consent form, PIS and GP leaflet for the above patient group.
27 October 2014	Protocol amended to v3.0. Study extension, and the addition of a healthy control group to undergo a one off ultrasound & whole body MRI for analysis.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported