Clinical trial results:
Safety and Efficacy of Calcipotriol plus Betamethasone Dipropionate Gel in Adolescent Patients (Aged 12 to 17 Years) with Scalp Psoriasis

Summary

EudraCT number	2008-005456-24
Trial protocol	FR GB
Global end of trial date	15 October 2012

Results information

Result version number	v1 (current)
This version publication date	01 February 2016
First version publication date	22 July 2015

Trial information

Trial identification

Sponsor protocol code	MBL 0412 INT

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	LEO Pharma A/S
Sponsor organisation address	Industriparken 55, Ballerup, Denmark,
Public contact	Clinical Trial Disclosure Manager, LEO Pharma A/S, +45 44945888, ctr.disclosure@leo-pharma.com
Scientific contact	Clinical Trial Disclosure Manager, LEO Pharma A/S, +45 44945888, ctr.disclosure@leo-pharma.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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	15 October 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 October 2012
Global end of trial reached?	Yes
Global end of trial date	15 October 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to evaluate the safety of once daily use of calcipotriol (50 mcg/g) plus betamethasone (0.5 mg/g) (as dipropionate) gel in adolescent subjects (aged 12 to 17 years) with scalp psoriasis.

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 November 2010
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: 37
Country: Number of subjects enrolled	France: 22
Country: Number of subjects enrolled	Canada: 19
Worldwide total number of subjects	78
EEA total number of subjects	59

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)	78
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Prior to Visit 1 (Day 0), a wash-out period (up to 8 weeks, as defined by the exclusion criteria) was to be completed if the subject had been treated with antipsoriatic treatments or other relevant medication; 2 screening visits were planned.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	LEO 80185 Gel Once Daily Application

Arm description:

Talconex® Scalp Topical Suspension/Daivobet® gel/Dovobet® gel/Xamiol® gel Calcipotriol 50 mcg/g plus betamethasone 0.5 mg/g (as dipropionate) gel once daily for up to 8 weeks to treat psoriasis on the scalp.

Arm type	Experimental
Investigational medicinal product name	LEO 80185 gel, calcipotriol 50 mcg/g plus betamethasone 0.5 mg/g (as dipropionate)
Investigational medicinal product code	
Other name	LEO 80185 gel
Pharmaceutical forms	Gel
Routes of administration	Cutaneous use

Dosage and administration details:

Applied once daily to lesions on the scalp, for up to 8 weeks

Number of subjects in period 1	LEO 80185 Gel Once Daily Application
Started	78
Completed	74
Not completed	4
Exclusion criteria emerging	2
Adverse event, non-fatal	1
Other reason(s)	1

Baseline characteristics

Reporting groups	
Reporting group title	LEO 80185 Gel Once Daily Application

Reporting group description:

Talconex® Scalp Topical Suspension/Daivobet® gel/Dovobet® gel/Xamiol® gel Calcipotriol 50 mcg/g plus betamethasone 0.5 mg/g (as dipropionate) gel once daily for up to 8 weeks to treat psoriasis on the scalp.

Reporting group values	LEO 80185 Gel Once Daily Application	Total	
Number of subjects	78	78	
Age categorical Units: Subjects			
Adolescents (12-17 years)	78	78	
Age continuous Units: years			
arithmetic mean	14.6		
standard deviation	± 1.7	-	
Gender categorical Units: Subjects			
Female	43	43	
Male	35	35	

End points

End points reporting groups

Reporting group title	LEO 80185 Gel Once Daily Application

Reporting group description:

Talconex® Scalp Topical Suspension/Daivobet® gel/Dovobet® gel/Xamiol® gel Calcipotriol 50 mcg/g plus betamethasone 0.5 mg/g (as dipropionate) gel once daily for up to 8 weeks to treat psoriasis on the scalp.

Primary: Percentage of Subjects with Adverse Drug Reactions (ADRs)

End point title	Percentage of Subjects with Adverse Drug Reactions (ADRs)[1]

End point description:

Adverse events for which the investigator did not describe the causal relationship to IP as not related

End point type	Primary

End point timeframe:

Throughout trial, up to 8 weeks

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There was no formal statistical hypothesis to be evaluated. The data were summarised using descriptive statistics.

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: Percent subjects				
number (not applicable)	6.4			

Statistical analyses

No statistical analyses for this end point

Primary: Change in Albumin-corrected Serum Calcium From Baseline to Week 4

End point title	Change in Albumin-corrected Serum Calcium From Baseline to Week 4[2]

End point description:

End point type	Primary

End point timeframe:

Baseline to Week 4

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There was no formal statistical hypothesis to be evaluated. The data were summarised using descriptive statistics.

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	77			
Units: mmol/L				
arithmetic mean (standard deviation)	-0.014 (± 0.139)			

Statistical analyses

No statistical analyses for this end point

Primary: Change in Albumin-corrected Serum Calcium From Baseline to Week 8

End point title	Change in Albumin-corrected Serum Calcium From Baseline to Week 8[3]

End point description:

End point type	Primary

End point timeframe:

Basline and week 8

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There was no formal statistical hypothesis to be evaluated. The data were summarised using descriptive statistics.

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: mmol/L				
arithmetic mean (standard deviation)	-0.002 (± 0.098)			

Statistical analyses

No statistical analyses for this end point

Primary: Change in Albumin-corrected Serum Calcium From Baseline to End of Treatment

End point title	Change in Albumin-corrected Serum Calcium From Baseline to End of Treatment[4]

End point description:

End point type	Primary

End point timeframe:

Baseline and End of treatment (up to 8 weeks)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There was no formal statistical hypothesis to be evaluated. The data were summarised using descriptive statistics.

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: mmol/L				
arithmetic mean (standard deviation)	0 (± 0.101)			

Statistical analyses

No statistical analyses for this end point

Primary: Change in 24-hour Urinary Calcium Excretion From Baseline to Week 4

End point title	Change in 24-hour Urinary Calcium Excretion From Baseline to Week 4[5]

End point description:

End point type	Primary

End point timeframe:

Baseline and week 4

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There was no formal statistical hypothesis to be evaluated. The data were summarised using descriptive statistics.

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	76			
Units: mmol/24hr				
arithmetic mean (standard deviation)	-0.01 (± 1.54)			

Statistical analyses

No statistical analyses for this end point

Primary: Change in 24-hour Urinary Calcium Excretion From Baseline to Week 8

End point title	Change in 24-hour Urinary Calcium Excretion From Baseline to Week 8[6]

End point description:

End point type	Primary

End point timeframe:

Basline and week 8

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There was no formal statistical hypothesis to be evaluated. The data were summarised using descriptive statistics.

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: mmol/24hr				
arithmetic mean (standard deviation)	0.03 (± 1.42)			

Statistical analyses

No statistical analyses for this end point

Primary: Change in 24-hour Urinary Calcium Excretion from Baseline to End of Treatment

End point title	Change in 24-hour Urinary Calcium Excretion from Baseline to End of Treatment[7]

End point description:

End point type	Primary

End point timeframe:

Baseline and End of Treatment (up to 8 weeks)

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There was no formal statistical hypothesis to be evaluated. The data were summarised using descriptive statistics.

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	77			
Units: mmol/24hr				
arithmetic mean (standard deviation)	-0.03 (± 1.43)			

Statistical analyses

No statistical analyses for this end point

Primary: Change in Urinary Calcium:Creatinine Ratio From Baseline to End of Treatment

End point title	Change in Urinary Calcium:Creatinine Ratio From Baseline to

	End of Treatment[8]

End point description:

End point type	Primary

End point timeframe:

Basline and End of Treatment

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There was no formal statistical hypothesis to be evaluated. The data were summarised using descriptive statistics.

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	77			
Units: mmol/g				
arithmetic mean (standard deviation)	-0.1156 (± 1.679)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Plasma parathyroid hormone (PTH) From Baseline to Week 4

End point title	Change in Plasma parathyroid hormone (PTH) From Baseline to Week 4

End point description:

End point type	Secondary

End point timeframe:

Baseline and week 4

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	74			
Units: ng/L				
arithmetic mean (standard deviation)	1.2 (± 16)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Plasma PTH From Baseline to Week 8

End point title	Change in Plasma PTH From Baseline to Week 8

End point description:

End point type	Secondary

End point timeframe:

Baseline and week 8

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	61			
Units: ng/L				
arithmetic mean (standard deviation)	-2.8 (± 13)			

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects With Controlled Disease (i.e. Clear or Almost Clear) According to the Investigator's Global Assessment (IGA) of Disease Severity at Week 2

End point title	Subjects With Controlled Disease (i.e. Clear or Almost Clear) According to the Investigator's Global Assessment (IGA) of Disease Severity at Week 2

End point description:

Disease severity of the scalp psoriasis as assessed by the 6-point scale IGA, based on the condition of the disease at the time of evaluation at week 2. The IGA Scale: 1 = clear, 2 = almost clear, 3 = mild, 4 = moderate, 5 = severe, and 6 = very severe.

End point type	Secondary

End point timeframe:

Week 2

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: Participants				
number (not applicable)	37			

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects With Controlled Disease (i.e., Clear or Almost Clear) According to the Investigator's Global Assessment (IGA) of Disease Severity at Week 4

End point title	Subjects With Controlled Disease (i.e., Clear or Almost Clear) According to the Investigator's Global Assessment (IGA) of Disease Severity at Week 4

End point description:

Disease severity of the scalp psoriasis as assessed by the 6-point scale IGA, based on the condition of the disease at the time of evaluation at week 4

End point type	Secondary

End point timeframe:

Week 4

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: Participants				
number (not applicable)	59			

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects With Controlled Disease (i.e., Clear or Almost Clear) According to the Investigator's Global Assessment (IGA) of Disease Severity at Week 8

End point title	Subjects With Controlled Disease (i.e., Clear or Almost Clear) According to the Investigator's Global Assessment (IGA) of Disease Severity at Week 8

End point description:

Disease severity of the scalp psoriasis as assessed by the 6-point scale IGA, based on the condition of the disease at the time of evaluation at week 8

End point type	Secondary

End point timeframe:

Week 8

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	61			
Units: Participants				
number (not applicable)	49			

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects With Controlled Disease (i.e., Clear or Almost Clear) According to the Investigator's Global Assessment (IGA) of Disease Severity at End of Treatment

End point title	Subjects With Controlled Disease (i.e., Clear or Almost Clear) According to the Investigator's Global Assessment (IGA) of Disease Severity at End of Treatment

End point description:

Disease severity of the scalp psoriasis as assessed by the 6-point scale IGA, based on the condition of the disease at the time of evaluation at end of treatment

End point type	Secondary

End point timeframe:

End of Treatment (up to 8 weeks)

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: Participants				
number (not applicable)	66			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Total Sign Score (TSS; Sum of Severity Scores for Each Individual Clinical Sign, Redness, Thickness, and Scaliness)From Baseline to Week 2

End point title	Percentage Change in Total Sign Score (TSS; Sum of Severity Scores for Each Individual Clinical Sign, Redness, Thickness, and Scaliness)From Baseline to Week 2

End point description:

Investigator assessment of scalp psoriasis lesions in terms of the three clinical signs: redness, thickness, and scaliness. Each clinical sign, a single score (ranging from 0 to 4), reflecting the average severity of all psoriatic lesions on the scalp, were determined. The sum of the three scores (redness, thickness, and scaliness) constitutes the Total Sign Score of the psoriasis on scalp, ranging from 0 (best possible outcome) to 12 points (worst possible outcome).

End point type	Secondary

End point timeframe:

Baseline and Week 2

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: Percentage of change				
arithmetic mean (standard deviation)	-62.7 (± 22.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Total Sign Score (TSS; Sum of Severity Scores for Each Individual Clinical Sign, Redness, Thickness, and Scaliness) From Baseline to Weeks 4

End point title	Percentage Change in Total Sign Score (TSS; Sum of Severity Scores for Each Individual Clinical Sign, Redness, Thickness, and Scaliness) From Baseline to Weeks 4

End point description:

Investigator assessment of scalp psoriasis lesions in terms of the three clinical signs: redness, thickness, and scaliness. Each clinical sign, a single score (ranging from 0 to 4), reflecting the average severity of all psoriatic lesions on the scalp, were determined. The sum of the three scores (redness, thickness, and scaliness) constitutes the Total Sign Score of the psoriasis on scalp, ranging from 0 to 12 points.

End point type	Secondary

End point timeframe:

Baseline and week 4

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: Percent of change				
arithmetic mean (standard deviation)	72.1 (± 21.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Total Sign Score (TSS; Sum of Severity Scores for Each Individual Clinical Sign, Redness, Thickness, and Scaliness) From Baseline to Week 8

End point title	Percentage Change in Total Sign Score (TSS; Sum of Severity Scores for Each Individual Clinical Sign, Redness, Thickness,

	and Scaliness) From Baseline to Week 8

End point description:

Investigator assessment of scalp psoriasis lesions in terms of the three clinical signs: redness, thickness, and scaliness. Each clinical sign, a single score (ranging from 0 to 4), reflecting the average severity of all psoriatic lesions on the scalp, were determined. The sum of the three scores (redness, thickness, and scaliness) constitutes the Total Sign Score of the psoriasis on scalp, ranging from 0 (best possible outcome) to 12 points (worst possible outcome).

End point type	Secondary

End point timeframe:

Baseline and week 8

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	61			
Units: Percent change				
arithmetic mean (standard deviation)	-76.6 (± 23.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Total Sign Score (TSS; Sum of Severity Scores for Each Individual Clinical Sign, Redness, Thickness, and Scaliness) From Baseline to End of Treatment.

End point title	Percentage Change in Total Sign Score (TSS; Sum of Severity Scores for Each Individual Clinical Sign, Redness, Thickness, and Scaliness) From Baseline to End of Treatment.

End point description:

Investigator assessment of scalp psoriasis lesions in terms of the three clinical signs: redness, thickness, and scaliness. Each clinical sign, a single score (ranging from 0 to 4), reflecting the average severity of all psoriatic lesions on the scalp, were determined. The sum of the three scores (redness, thickness, and scaliness) constitutes the Total Sign Score of the psoriasis on scalp, ranging from 0 (best possible outcome) to 12 points (worst possible outcome).

End point type	Secondary

End point timeframe:

Baseline and End of Treatment (up to 8 weeks)

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: Percent of change				
arithmetic mean (standard deviation)	80.4 (± 22.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects With Controlled Disease (Defined as Clear or Very Mild) According to the Patient's Global Assessment of Disease Severity at Week 2

End point title	Subjects With Controlled Disease (Defined as Clear or Very Mild) According to the Patient's Global Assessment of Disease Severity at Week 2

End point description:

Disease severity of the scalp psoriasis as assessed by the 5-point scale, Patient's Global Assessment of Disease Severity, based on the condition of the disease at the time of evaluation. The scale: 1 = clear, 2 = very mild, 3 = mild, 4 = moderate, 5 = severe

End point type	Secondary

End point timeframe:

Week 2

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: Participants				
number (not applicable)	44			

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects With Controlled Disease (Defined as Clear or Very Mild) According to the Patient's Global Assessment of Disease Severity at Week 4

End point title	Subjects With Controlled Disease (Defined as Clear or Very Mild) According to the Patient's Global Assessment of Disease Severity at Week 4

End point description:

Disease severity of the scalp psoriasis as assessed by the 5-point scale, Patient's Global Assessment of Disease Severity, based on the condition of the disease at the time of evaluation.

End point type	Secondary

End point timeframe:

Week 4

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: Participants				
number (not applicable)	55			

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects With Controlled Disease (Defined as Clear or Very Mild) According to the Patient's Global Assessment of Disease Severity at Week 8

End point title	Subjects With Controlled Disease (Defined as Clear or Very Mild) According to the Patient's Global Assessment of Disease Severity at Week 8

End point description:

Disease severity of the scalp psoriasis as assessed by the 5-point scale, Patient's Global Assessment of Disease Severity, based on the condition of the disease at the time of evaluation.

End point type	Secondary

End point timeframe:

Week 8

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	61			
Units: Participants				
number (not applicable)	51			

Statistical analyses

No statistical analyses for this end point

Secondary: Subjects With Controlled Disease (Defined as Clear or Very Mild) According to the Patient's Global Assessment of Disease Severity at End of Treatment

End point title	Subjects With Controlled Disease (Defined as Clear or Very Mild) According to the Patient's Global Assessment of Disease Severity at End of Treatment

End point description:

Disease severity of the scalp psoriasis as assessed by the 5-point scale, Patient's Global Assessment of Disease Severity, based on the condition of the disease at the time of evaluation.

End point type	Secondary

End point timeframe:

End of Treatment (up to 8 weeks)

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: Participants				
number (not applicable)	68			

Statistical analyses

No statistical analyses for this end point

Secondary: Withdrawal

End point title	Withdrawal

End point description:

How many subjects withdrew from the study. Reasons for withdrawal: due to exclusion criteria emerging, due to AE(s), or due to other reason

End point type	Secondary

End point timeframe:

Week 4 and 8

End point values	LEO 80185 Gel Once Daily Application			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: Participants				
number (not applicable)	4			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Throughout the trial, up to 8 weeks	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	14.1
Reporting groups	
Reporting group title	LEO 80185 Gel Once Daily Application
Reporting group description: Talconex® Scalp Topical Suspension/Daivobet® gel/Dovobet® gel/Xamiol® gel Calcipotriol 50 mcg/g plus betamethasone 0.5 mg/g (as dipropionate) gel once daily for up to 8 weeks to treat psoriasis on the scalp.	

Serious adverse events	LEO 80185 Gel Once Daily Application		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 78 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	LEO 80185 Gel Once Daily Application		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 78 (12.82%)		
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 78 (5.13%)		
occurrences (all)	5		
Infections and infestations			
Pharyngitis			
subjects affected / exposed	4 / 78 (5.13%)		
occurrences (all)	4		
Upper respiratory tract infection			
subjects affected / exposed	4 / 78 (5.13%)		
occurrences (all)	4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 June 2010	The duration of the wash-out period extended to up to 8 weeks (were up to 5 weeks), making the maximum duration of the trial period for each subject 20 weeks (were 17 weeks). Informed consent for minors that became legally emancipated was added, so that a subject, who previously gave assent, during the trial became legally emancipated was to be asked to provide their written consent.
11 August 2010	In the instruction to the Treatment Period the following was added: 'Subjects should be instructed to discontinue treatment on individual lesions if/when a lesion has cleared'. The following calculations from the 24-hour urine sample were added: calcium:creatinine, phophate:creatinine, hydroxyproline:creatinine, and sodium:creatinine ratios. The wording of the definition of clear in erythema was clarified. Cortisol was added to the biochemistry assessment.
05 January 2011	Canada was added as a country. Inclusion Criterion No. 6 was amended to 'Clinical diagnosis of psoriasis vulgaris as evidenced by scalp psoriasis lesions of typical appearance or clinical signs of psoriasis vulgaris on trunk and/or limbs, or earlier diagnosed with psoriasis vulgaris on trunk and/or limbs.' Inclusion Criterion No. 8 was amended to 'Attending a hospital out-patient clinic or the private practice of a dermatologist or in the UK a General Practitioner with Special Interest in Dermatology (GPwSI).' .
21 November 2011	The number of sites to include subjects were changed to 36 sites and Germany was added as a country (although no sites in Germany were used). Exclusion Criterion No. 16 was amended to 'Any clinically significant abnormality following review of screening laboratory tests (blood and spot urine samples, not including 24-hour urine sample), physical examination or blood pressure/heart rate measurement performed at SV2.'). An Exclusion Criterion No. 23 was added: 'Subjects who are institutionalised by court order or by the local authority.' `The following were to be analysed quantitatively in the 24-hour urine sample: ` was added

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported