Clinical trial results:
A psoriasis plaque test trial with LP0113 spray in patients with psoriasis vulgaris

Summary

EudraCT number	2014-004759-30
Trial protocol	FR
Global end of trial date	30 June 2015

Results information

Result version number	v1 (current)
This version publication date	09 July 2016
First version publication date	09 July 2016

Trial information

Trial identification

Sponsor protocol code	LP0113-1123

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02416258
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	LEO Pharma A/S
Sponsor organisation address	Industriparken 55, Ballerup, Denmark, 2750
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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 May 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 June 2015
Global end of trial reached?	Yes
Global end of trial date	30 June 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the anti-psoriatic effect of LP0113 aerosol spray compared to Daivobet® gel, LEO 90100 aerosol foam, betamethasone dipropionate (BDP) in the aerosol spray vehicle, calcipotriol in the aerosol spray vehicle and aerosol spray vehicle.

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 April 2015
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	France: 50
Worldwide total number of subjects	50
EEA total number of subjects	50

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)	38
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

50 subjects from 1 centre in France were enrolled into the trial. The first subject was enrolled on 02-Apr-2015 and the last subject completed the trial (last visit, including follow-up) on 30-Jun-2015.

Pre-assignment

Screening details:

Screening assessments could occur up to 28 days prior to the Day 1 Visit (Visit 2; hereafter "Baseline"). At the Screening Visit, 1 to 6 lesions ("target plaques") were identified on the arms, legs and/or trunk of the subject and monitored until the Baseline Visit when the 6 test sites to be treated with IMP were identified. No screening failures.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Investigator[1]

Blinding implementation details:

Due to the different formulations of some of the IMPs (foam, spray, gel), a fully double blinded design was not possible and the trial was performed as an investigator-blinded trial.

Arms

Are arms mutually exclusive?	No
Arm title	LP0113 aerosol spray

Arm description:

Each subject was treated with the 6 products on 6 test sites (each 5 cm2) which were located within 1 to 6 stable psoriasis lesions (target plaques) on arms, legs and/or trunk. An application scheme showed which treatment should be applied to each test site. The test sites were marked with a numbered, disposable circular device, which was attached to the skin; the outline of each circular device was drawn on the skin using an indelible marker.

IMP was applied by site staff once daily 6 days a week for 4 weeks. A blinded investigator assessed test sites twice weekly for the severity of the clinical signs erythema, scaling, and infiltration.

LP0113 aerosol spray contains calcipotriol (as monohydrate) 50 mcg/g and betamethasone (as dipropionate) 0.5 mg/g.

Arm type	Experimental
Investigational medicinal product name	LP0113 aerosol spray
Investigational medicinal product code	LP0113
Other name	
Pharmaceutical forms	Cutaneous spray
Routes of administration	Topical use

Dosage and administration details:

LP0113, LEO 90100, BDP in aerosol spray vehicle, calcipotriol in aerosol spray vehicle, and the aerosol spray vehicle were sprayed on the test sites and gently rubbed into the skin using a gloved finger (1 finger for each product). Each test site was treated with 50 mg degassed spray or foam. Finally, all test sites were covered with a non-occlusive gauze maintained with an hypoallergenic dressing.
At visits which only included application of IMPs, the non-occlusive gauze was removed from the test sites using a small pair of scissors. IMPs were then applied as described above and new non-occlusive gauze was applied to the test sites and attached using a hypoallergenic dressing.
At visits which included both application of IMPs and clinical assessments, the non-occlusive gauze and the circular devices were removed prior to the assessments by the blinded investigator; following the assessments, the circular devices were replaced with new ones and IMPs were applied as described above.

Arm title	Daivobet® gel

Arm description:

Each subject was treated with the 6 products on 6 test sites (each 5 cm2) which were located within 1 to 6 stable psoriasis lesions (target plaques) on arms, legs and/or trunk. An application scheme showed which treatment should be applied to each test site. The test sites were marked with a numbered, disposable circular device, which was attached to the skin; the outline of each circular device was drawn on the skin using an indelible marker.

IMP was applied by site staff once daily 6 days a week for 4 weeks. A blinded investigator assessed test sites twice weekly for the severity of the clinical signs erythema, scaling, and infiltration.

Daivobet® gel contains calcipotriol (as monohydrate) 50 mcg/g and betamethasone (as dipropionate) 0.5 mg/g.

Arm type	Active comparator
Investigational medicinal product name	Daivobet® gel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Daivobet® gel was applied using an Eppendorf combitip® (50 µl per application). Finally, all test sites were covered with a non-occlusive gauze maintained with an hypoallergenic dressing.
At visits which only included application of IMPs, the non-occlusive gauze was removed from the test sites using a small pair of scissors. IMPs were then applied as described above and new non-occlusive gauze was applied to the test sites and attached using a hypoallergenic dressing.
At visits which included both application of IMPs and clinical assessments, the non-occlusive gauze and the circular devices were removed prior to the assessments by the blinded investigator; following the assessments, the circular devices were replaced with new ones and IMPs were applied as described above.

Arm title	LEO 90100

Arm description:

Each subject was treated with the 6 products on 6 test sites (each 5 cm2) which were located within 1 to 6 stable psoriasis lesions (target plaques) on arms, legs and/or trunk. An application scheme showed which treatment should be applied to each test site. The test sites were marked with a numbered, disposable circular device, which was attached to the skin; the outline of each circular device was drawn on the skin using an indelible marker.

IMP was applied by site staff once daily 6 days a week for 4 weeks. A blinded investigator assessed test sites twice weekly for the severity of the clinical signs erythema, scaling, and infiltration.

LEO 90100 contains calcipotriol (as monohydrate) 50 mcg/g and betamethasone (as dipropionate) 0.5 mg/g.

Arm type	Active comparator
Investigational medicinal product name	LEO 90100
Investigational medicinal product code	LEO 90100
Other name	Enstilar® foam
Pharmaceutical forms	Cutaneous foam
Routes of administration	Topical use

Dosage and administration details:

LP0113, LEO 90100, BDP in aerosol spray vehicle, calcipotriol in aerosol spray vehicle, and the aerosol spray vehicle were sprayed on the test sites and gently rubbed into the skin using a gloved finger (1 finger for each product). Each test site was treated with 50 mg degassed spray or foam. Finally, all test sites were covered with a non-occlusive gauze maintained with an hypoallergenic dressing.
At visits which only included application of IMPs, the non-occlusive gauze was removed from the test sites using a small pair of scissors. IMPs were then applied as described above and new non-occlusive gauze was applied to the test sites and attached using a hypoallergenic dressing.
At visits which included both application of IMPs and clinical assessments, the non-occlusive gauze and the circular devices were removed prior to the assessments by the blinded investigator; following the assessments, the circular devices were replaced with new ones and IMPs were applied as described above.

Arm title	BDP aerosol spray

Arm description:

Betamethasone dipropionate (BDP) in aerosol spray vehicle

Each subject was treated with the 6 products on 6 test sites (each 5 cm2) which were located within 1 to 6 stable psoriasis lesions (target plaques) on arms, legs and/or trunk. An application scheme showed which treatment should be applied to each test site. The test sites were marked with a numbered, disposable circular device, which was attached to the skin; the outline of each circular device was drawn on the skin using an indelible marker.

IMP was applied by site staff once daily 6 days a week for 4 weeks. A blinded investigator assessed test sites twice weekly for the severity of the clinical signs erythema, scaling, and infiltration.

BDP in aerosol spray contains betamethasone (as dipropionate) 0.5 mg/g.

Arm type	Active comparator
Investigational medicinal product name	BDP aerosol spray
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous spray
Routes of administration	Topical use

Dosage and administration details:

LP0113, LEO 90100, BDP in aerosol spray vehicle, calcipotriol in aerosol spray vehicle, and the aerosol spray vehicle were sprayed on the test sites and gently rubbed into the skin using a gloved finger (1 finger for each product). Each test site was treated with 50 mg degassed spray or foam. Finally, all test sites were covered with a non-occlusive gauze maintained with an hypoallergenic dressing.
At visits which only included application of IMPs, the non-occlusive gauze was removed from the test sites using a small pair of scissors. IMPs were then applied as described above and new non-occlusive gauze was applied to the test sites and attached using a hypoallergenic dressing.
At visits which included both application of IMPs and clinical assessments, the non-occlusive gauze and the circular devices were removed prior to the assessments by the blinded investigator; following the assessments, the circular devices were replaced with new ones and IMPs were applied as described above.

Arm title	Calcipotriol aerosol spray

Arm description:

Calcipotriol in aerosol spray vehicle

Each subject was treated with the 6 products on 6 test sites (each 5 cm2) which were located within 1 to 6 stable psoriasis lesions (target plaques) on arms, legs and/or trunk. An application scheme showed which treatment should be applied to each test site. The test sites were marked with a numbered, disposable circular device, which was attached to the skin; the outline of each circular device was drawn on the skin using an indelible marker.

IMP was applied by site staff once daily 6 days a week for 4 weeks. A blinded investigator assessed test sites twice weekly for the severity of the clinical signs erythema, scaling, and infiltration.

Calcipotriol in aerosol spray contains calcipotriol (as monohydrate) 50 mcg/g

Arm type	Active comparator
Investigational medicinal product name	Calcipotriol aerosol spray
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous spray
Routes of administration	Topical use

Dosage and administration details:

LP0113, LEO 90100, BDP in aerosol spray vehicle, calcipotriol in aerosol spray vehicle, and the aerosol spray vehicle were sprayed on the test sites and gently rubbed into the skin using a gloved finger (1 finger for each product). Each test site was treated with 50 mg degassed spray or foam. Finally, all test sites were covered with a non-occlusive gauze maintained with an hypoallergenic dressing.
At visits which only included application of IMPs, the non-occlusive gauze was removed from the test sites using a small pair of scissors. IMPs were then applied as described above and new non-occlusive gauze was applied to the test sites and attached using a hypoallergenic dressing.
At visits which included both application of IMPs and clinical assessments, the non-occlusive gauze and the circular devices were removed prior to the assessments by the blinded investigator; following the assessments, the circular devices were replaced with new ones and IMPs were applied as described above.

Arm title	Aerosol spray vehicle

Arm description:

Each subject was treated with the 6 products on 6 test sites (each 5 cm2) which were located within 1 to 6 stable psoriasis lesions (target plaques) on arms, legs and/or trunk. An application scheme showed which treatment should be applied to each test site. The test sites were marked with a numbered, disposable circular device, which was attached to the skin; the outline of each circular device was drawn on the skin using an indelible marker.

IMP was applied by site staff once daily 6 days a week for 4 weeks. A blinded investigator assessed test sites twice weekly for the severity of the clinical signs erythema, scaling, and infiltration.

Arm type	Placebo
Investigational medicinal product name	Aerosol spray vehicle
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous spray
Routes of administration	Topical use

Dosage and administration details:

LP0113, LEO 90100, BDP in aerosol spray vehicle, calcipotriol in aerosol spray vehicle, and the aerosol spray vehicle were sprayed on the test sites and gently rubbed into the skin using a gloved finger (1 finger for each product). Each test site was treated with 50 mg degassed spray or foam. Finally, all test sites were covered with a non-occlusive gauze maintained with an hypoallergenic dressing.
At visits which only included application of IMPs, the non-occlusive gauze was removed from the test sites using a small pair of scissors. IMPs were then applied as described above and new non-occlusive gauze was applied to the test sites and attached using a hypoallergenic dressing.
At visits which included both application of IMPs and clinical assessments, the non-occlusive gauze and the circular devices were removed prior to the assessments by the blinded investigator; following the assessments, the circular devices were replaced with new ones and IMPs were applied as described above.

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: Due to the different formulations of some of the IMPs (foam, spray, gel), a fully double blinded design was not possible and the trial was performed as an investigator-blinded trial.

Number of subjects in period 1	LP0113 aerosol spray	Daivobet® gel	LEO 90100
Started	50	50	50
Completed	50	50	50

Number of subjects in period 1	BDP aerosol spray	Calcipotriol aerosol spray	Aerosol spray vehicle
Started	50	50	50
Completed	50	50	50

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	50	50	
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)	38	38	
From 65-84 years	12	12	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	52.3		
standard deviation	± 13.6	-	
Gender categorical Units: Subjects			
Female	21	21	
Male	29	29	

End points

End points reporting groups

Reporting group title	LP0113 aerosol spray

Reporting group description:

Each subject was treated with the 6 products on 6 test sites (each 5 cm2) which were located within 1 to 6 stable psoriasis lesions (target plaques) on arms, legs and/or trunk. An application scheme showed which treatment should be applied to each test site. The test sites were marked with a numbered, disposable circular device, which was attached to the skin; the outline of each circular device was drawn on the skin using an indelible marker.

IMP was applied by site staff once daily 6 days a week for 4 weeks. A blinded investigator assessed test sites twice weekly for the severity of the clinical signs erythema, scaling, and infiltration.

LP0113 aerosol spray contains calcipotriol (as monohydrate) 50 mcg/g and betamethasone (as dipropionate) 0.5 mg/g.

Reporting group title	Daivobet® gel

Reporting group description:

Each subject was treated with the 6 products on 6 test sites (each 5 cm2) which were located within 1 to 6 stable psoriasis lesions (target plaques) on arms, legs and/or trunk. An application scheme showed which treatment should be applied to each test site. The test sites were marked with a numbered, disposable circular device, which was attached to the skin; the outline of each circular device was drawn on the skin using an indelible marker.

IMP was applied by site staff once daily 6 days a week for 4 weeks. A blinded investigator assessed test sites twice weekly for the severity of the clinical signs erythema, scaling, and infiltration.

Daivobet® gel contains calcipotriol (as monohydrate) 50 mcg/g and betamethasone (as dipropionate) 0.5 mg/g.

Reporting group title	LEO 90100

Reporting group description:

Each subject was treated with the 6 products on 6 test sites (each 5 cm2) which were located within 1 to 6 stable psoriasis lesions (target plaques) on arms, legs and/or trunk. An application scheme showed which treatment should be applied to each test site. The test sites were marked with a numbered, disposable circular device, which was attached to the skin; the outline of each circular device was drawn on the skin using an indelible marker.

IMP was applied by site staff once daily 6 days a week for 4 weeks. A blinded investigator assessed test sites twice weekly for the severity of the clinical signs erythema, scaling, and infiltration.

LEO 90100 contains calcipotriol (as monohydrate) 50 mcg/g and betamethasone (as dipropionate) 0.5 mg/g.

Reporting group title	BDP aerosol spray

Reporting group description:

Betamethasone dipropionate (BDP) in aerosol spray vehicle

Each subject was treated with the 6 products on 6 test sites (each 5 cm2) which were located within 1 to 6 stable psoriasis lesions (target plaques) on arms, legs and/or trunk. An application scheme showed which treatment should be applied to each test site. The test sites were marked with a numbered, disposable circular device, which was attached to the skin; the outline of each circular device was drawn on the skin using an indelible marker.

IMP was applied by site staff once daily 6 days a week for 4 weeks. A blinded investigator assessed test sites twice weekly for the severity of the clinical signs erythema, scaling, and infiltration.

BDP in aerosol spray contains betamethasone (as dipropionate) 0.5 mg/g.

Reporting group title	Calcipotriol aerosol spray

Reporting group description:

Calcipotriol in aerosol spray vehicle

Each subject was treated with the 6 products on 6 test sites (each 5 cm2) which were located within 1 to 6 stable psoriasis lesions (target plaques) on arms, legs and/or trunk. An application scheme showed which treatment should be applied to each test site. The test sites were marked with a numbered,

disposable circular device, which was attached to the skin; the outline of each circular device was drawn on the skin using an indelible marker.

IMP was applied by site staff once daily 6 days a week for 4 weeks. A blinded investigator assessed test sites twice weekly for the severity of the clinical signs erythema, scaling, and infiltration.

Calcipotriol in aerosol spray contains calcipotriol (as monohydrate) 50 mcg/g

Reporting group title	Aerosol spray vehicle

Reporting group description:

Each subject was treated with the 6 products on 6 test sites (each 5 cm2) which were located within 1 to 6 stable psoriasis lesions (target plaques) on arms, legs and/or trunk. An application scheme showed which treatment should be applied to each test site. The test sites were marked with a numbered, disposable circular device, which was attached to the skin; the outline of each circular device was drawn on the skin using an indelible marker.

IMP was applied by site staff once daily 6 days a week for 4 weeks. A blinded investigator assessed test sites twice weekly for the severity of the clinical signs erythema, scaling, and infiltration.

Primary: Absolute Change in Total Clinical Score of Clinical Signs at End of Treatment Compared to Baseline

End point title	Absolute Change in Total Clinical Score of Clinical Signs at End of Treatment Compared to Baseline

End point description:

The severity of the clinical signs erythema, scaling, and infiltration was assessed on a 7-point scale ranging from 0 (no evidence) to 3 (severe) [0, 0.5, 1, 1.5, 2, 2.5, 3]. The Total Clinical Score (TCS) was obtained by summing the scores for erythema, scaling, and infiltration and could range from 0 to 9. Treatment differences were tested as contrasts using a two-way ANOVA with treatment and subject as fixed effects. As the purpose of this trial was to obtain preliminary clinical estimates of effect, no correction to multiplicity was made in the primary analysis. A secondary analysis using Tukey's honestly significant difference (HSD) method for correcting p-values was produced in the two-way ANOVA.

End point type	Primary

End point timeframe:

4 weeks

End point values	LP0113 aerosol spray	Daivobet® gel	LEO 90100	BDP aerosol spray
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	50	50
Units: Total Clinical Score				
arithmetic mean (standard deviation)				
Baseline	6.5 (± 0.8)	6.5 (± 0.8)	6.4 (± 0.8)	6.4 (± 0.8)
Day 29 (Change from Baseline)	-5.4 (± 1.3)	-5 (± 1.6)	-5.9 (± 0.8)	-5.2 (± 1.3)

End point values	Calcipotriol aerosol spray	Aerosol spray vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Total Clinical Score				
arithmetic mean (standard deviation)				
Baseline	6.4 (± 0.8)	6.4 (± 0.8)		
Day 29 (Change from Baseline)	-3.1 (± 1.9)	-1.6 (± 1.5)		

Statistical analyses

Statistical analysis title	TCS comparison LP0113 vs Vehicle

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LP0113 aerosol spray - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	LP0113 aerosol spray v Aerosol spray vehicle
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [1]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-3.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.3
upper limit	-3.32

Notes:

[1] - Statistically significant superiority of LP0113 aerosol spray over Aerosol spray vehicle

Statistical analysis title	TCS comparison Daivobet vs Vehicle

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (Daivobet® gel - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v Daivobet® gel
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [2]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-3.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.91
upper limit	-2.93

Notes:

[2] - Statistically significant superiority of Daivobet® gel over Aerosol spray vehicle

Statistical analysis title	TCS comparison LEO 90100 vs Vehicle

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LEO 90100 - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v LEO 90100
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [3]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-4.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.85
upper limit	-3.87

Notes:

[3] - Statistically significant superiority of LEO 90100 over Aerosol spray vehicle

Statistical analysis title	TCS comparison BDP vs Vehicle

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (BDP aerosol spray - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v BDP aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [4]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-3.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.13
upper limit	-3.15

Notes:

[4] - Statistically significant superiority of BDP aerosol spray over Aerosol spray vehicle

Statistical analysis title	TCS comparison Calcipotriol vs Vehicle

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (Calcipotriol aerosol spray - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v Calcipotriol aerosol spray

Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [5]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.02
upper limit	-1.04

Notes:

[5] - Statistically significant superiority of Calcipotriol aerosol spray over Aerosol spray vehicle

Statistical analysis title	TCS comparison LP0113 vs Calcipotriol

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LP0113 aerosol spray - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v LP0113 aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [6]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-2.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.77
upper limit	-1.79

Notes:

[6] - Statistically significant superiority of LP0113 aerosol spray over Calcipotriol aerosol spray

Statistical analysis title	TCS comparison Daivobet vs Calcipotriol

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (Daivobet® gel - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v Daivobet® gel
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [7]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.89

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.38
upper limit	-1.4

Notes:

[7] - Statistically significant superiority of Daivobet® gel over Calcipotriol aerosol spray

Statistical analysis title	TCS comparison LEO 90100 vs Calcipotriol

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LEO 90100 - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v LEO 90100
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [8]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-2.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.32
upper limit	-2.34

Notes:

[8] - Statistically significant superiority of LEO 90100 over Calcipotriol aerosol spray

Statistical analysis title	TCS comparison BDP vs Calcipotriol

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (BDP aerosol spray - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v BDP aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [9]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-2.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	-1.62

Notes:

[9] - Statistically significant superiority of BDP aerosol spray over Calcipotriol aerosol spray

Statistical analysis title	TCS comparison LP0113 vs BDP

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LP0113 aerosol spray - BDP aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	BDP aerosol spray v LP0113 aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.66
upper limit	0.32

Statistical analysis title	TCS comparison Daivobet vs BDP

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (Daivobet® gel - BDP aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	BDP aerosol spray v Daivobet® gel
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.38
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.27
upper limit	0.71

Statistical analysis title	TCS comparison LEO 90100 vs BDP

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LEO 90100 - BDP aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	BDP aerosol spray v LEO 90100

Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004 [10]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.21
upper limit	-0.23

Notes:

[10] - Statistically significant superiority of LEO 90100 over BDP aerosol spray

Statistical analysis title	TCS comparison LP0113 vs LEO 90100

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LP0113 aerosol spray - LEO 90100).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	LEO 90100 v LP0113 aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.028 [11]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	0.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	1.04

Notes:

[11] - Statistically significant superiority of LEO 90100 over LP0113 aerosol spray

Statistical analysis title	TCS comparison Daivobet vs LEO 90100

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (Daivobet® gel - LEO 90100).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	LEO 90100 v Daivobet® gel
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [12]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	0.94

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	1.43

Notes:

[12] - Statistically significant superiority of LEO 90100 over Daivobet® gel

Statistical analysis title	TCS comparison LP0113 vs Daivobet

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LP0113 aerosol spray - Daivobet® gel).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Daivobet® gel v LP0113 aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.12
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.88
upper limit	0.1

Statistical analysis title	TCS comparison LP0113 vs Vehicle - Tukey

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LP0113 aerosol spray - Vehicle aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	LP0113 aerosol spray v Aerosol spray vehicle
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [13]
Method	ANOVA
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.53
upper limit	-3.09

Notes:

[13] - Corrected P-values and confidence intervals using Tukeys honestly significant difference method. Statistically significant superiority of LP0113 aerosol spray over Aerosol spray vehicle

Statistical analysis title	TCS comparison Daivobet vs Vehicle - Tukey

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (Daivobet® gel - Vehicle aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v Daivobet® gel
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [14]
Method	ANOVA
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.14
upper limit	-2.7

Notes:

[14] - Corrected P-values and confidence intervals using Tukeys honestly significant difference method. Statistically significant superiority of Daivobet® gel over Aerosol spray vehicle

Statistical analysis title	TCS comparison LEO 90100 vs Vehicle - Tukey

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LEO 90100 - Vehicle aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v LEO 90100
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [15]
Method	ANOVA
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.08
upper limit	-3.64

Notes:

[15] - Corrected P-values and confidence intervals using Tukeys honestly significant difference method. Statistically significant superiority of LEO 90100 over Aerosol spray vehicle

Statistical analysis title	TCS comparison Calcipotriol vs Vehicle - Tukey

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (Calcipotriol aerosol spray - Vehicle aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v Calcipotriol aerosol spray

Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [16]
Method	ANOVA
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.25
upper limit	-0.81

Notes:

[16] - Corrected P-values and confidence intervals using Tukeys honestly significant difference method. Statistically significant superiority of Calcipotriol aerosol spray over Aerosol spray vehicle

Statistical analysis title	TCS comparison LP0113 vs Calcipotriol - Tukey

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LP0113 aerosol spray - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v LP0113 aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [17]
Method	ANOVA
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	-1.56

Notes:

[17] - Corrected P-values and confidence intervals using Tukeys honestly significant difference method. Statistically significant superiority of LP0113 aerosol spray over Calcipotriol aerosol spray

Statistical analysis title	TCS comparison BDP vs Vehicle - Tukey

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (BDP aerosol spray - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v BDP aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [18]
Method	ANOVA
Parameter estimate	Mean difference (net)

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.36
upper limit	-2.92

Notes:

[18] - Corrected P-values and confidence intervals using Tukeys honestly significant difference method. Statistically significant superiority of BDP aerosol spray over Aerosol spray vehicle

Statistical analysis title	TCS comparison Daivobet vs Calcipotriol - Tukey

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (Daivobet® gel - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v Daivobet® gel
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [19]
Method	ANOVA
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.61
upper limit	-1.17

Notes:

[19] - Corrected P-values and confidence intervals using Tukeys honestly significant difference method. Statistically significant superiority of Daivobet® gel over Calcipotriol aerosol spray

Statistical analysis title	TCS comparison LEO 90100 vs Calcipotriol - Tukey

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LEO 90100 - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v LEO 90100
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [20]
Method	ANOVA
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.55
upper limit	-2.11

Notes:

[20] - Corrected P-values and confidence intervals using Tukeys honestly significant difference method. Statistically significant superiority of LEO 90100 over Calcipotriol aerosol spray

Statistical analysis title	TCS comparison BDP vs Calcipotriol - Tukey

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (BDP aerosol spray - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v BDP aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [21]
Method	ANOVA
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.83
upper limit	-1.39

Notes:

[21] - Corrected P-values and confidence intervals using Tukeys honestly significant difference method. Statistically significant superiority of BDP aerosol spray over Calcipotriol aerosol spray

Statistical analysis title	TCS comparison LP0113 vs BDP - Tukey

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LP0113 aerosol spray - BDP aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	BDP aerosol spray v LP0113 aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.98 [22]
Method	ANOVA
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.89
upper limit	0.55

Notes:

[22] - Corrected P-values and confidence intervals using Tukeys honestly significant difference method.

Statistical analysis title	TCS comparison Daivobet vs BDP - Tukey

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (Daivobet® gel - BDP aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	BDP aerosol spray v Daivobet® gel

Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.95 [23]
Method	ANOVA
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	0.94

Notes:

[23] - Corrected P-values and confidence intervals using Tukeys honestly significant difference method.

Statistical analysis title	TCS comparison LEO 90100 vs BDP - Tukey

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LEO 90100 - BDP aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	BDP aerosol spray v LEO 90100
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.048 [24]
Method	ANOVA
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.44
upper limit	0

Notes:

[24] - Corrected P-values and confidence intervals using Tukeys honestly significant difference method. Statistically significant superiority of LEO 90100 over BDP aerosol spray

Statistical analysis title	TCS comparison LP0113 vs LEO 90100 - Tukey

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LP0113 aerosol spray - LEO 90100).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	LEO 90100 v LP0113 aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.24 [25]
Method	ANOVA
Parameter estimate	Mean difference (net)

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.17
upper limit	1.27

Notes:

[25] - Corrected P-values and confidence intervals using Tukeys honestly significant difference method.

Statistical analysis title	TCS comparison Daivobet vs LEO 90100 - Tukey

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (Daivobet® gel - LEO 90100).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	LEO 90100 v Daivobet® gel
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [26]
Method	ANOVA
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.22
upper limit	1.66

Notes:

[26] - Corrected P-values and confidence intervals using Tukeys honestly significant difference method.
Statistically significant superiority of LEO 90100 over Daivobet® gel

Statistical analysis title	TCS comparison LP0113 vs Daivobet - Tukey

Statistical analysis description:

Between treatment difference in absolute change in TCS from baseline to end of treatment (LP0113 aerosol spray - Daivobet® gel).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Daivobet® gel v LP0113 aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.62 [27]
Method	ANOVA
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.11
upper limit	0.33

Notes:

[27] - Corrected P-values and confidence intervals using Tukeys honestly significant difference method.

Secondary: Absolute Change in Total Clinical Score at Individual Visits Compared to Baseline

End point title	Absolute Change in Total Clinical Score at Individual Visits Compared to Baseline

End point description:

Total Clinical Score (TCS) of clinical signs (sum of erythema, scaling, and infiltration) could range from 0 to 9.

End point type	Secondary

End point timeframe:

4 weeks

End point values	LP0113 aerosol spray	Daivobet® gel	LEO 90100	BDP aerosol spray
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	50	50
Units: Total Clinical Score				
arithmetic mean (standard deviation)				
Baseline	6.5 (± 0.8)	6.5 (± 0.8)	6.4 (± 0.8)	6.4 (± 0.7)
Day 4 (Change from Baseline)	-0.9 (± 1.2)	-1 (± 1.1)	-1.6 (± 1.5)	-0.8 (± 1.1)
Day 8 (Change from Baseline)	-2.5 (± 1.5)	-2.1 (± 1.3)	-3.1 (± 1.3)	-2 (± 1.5)
Day 11 (Change from Baseline)	-3.5 (± 1.8)	-3 (± 1.3)	-4.1 (± 1.3)	-3 (± 1.8)
Day 15 (Change from Baseline)	-4.2 (± 1.7)	-3.6 (± 1.5)	-4.8 (± 1.1)	-3.6 (± 1.9)
Day 18 (Change from Baseline)	-4.7 (± 1.4)	-4.3 (± 1.6)	-5.3 (± 1.1)	-4.3 (± 1.7)
Day 22 (Change from Baseline)	-4.9 (± 1.4)	-4.5 (± 1.7)	-5.5 (± 1)	-4.8 (± 1.4)
Day 25 (Change from Baseline)	-5.2 (± 1.3)	-4.9 (± 1.6)	-4.9 (± 1.6)	-5 (± 1.3)
Day 29 (Change from Baseline)	-5.4 (± 1.3)	-5 (± 1.6)	-5.9 (± 0.8)	-5.2 (± 1.3)

End point values	Calcipotriol aerosol spray	Aerosol spray vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Total Clinical Score				
arithmetic mean (standard deviation)				
Baseline	6.4 (± 0.7)	6.4 (± 0.8)		
Day 4 (Change from Baseline)	-0.3 (± 0.8)	-0.4 (± 0.7)		
Day 8 (Change from Baseline)	-0.9 (± 1.1)	-0.5 (± 1)		
Day 11 (Change from Baseline)	-1.4 (± 1.1)	-1 (± 1.1)		
Day 15 (Change from Baseline)	-2 (± 1.4)	-1.1 (± 1.2)		
Day 18 (Change from Baseline)	-2.4 (± 1.5)	-1.4 (± 1.3)		
Day 22 (Change from Baseline)	-2.6 (± 1.4)	-1.2 (± 1.4)		
Day 25 (Change from Baseline)	-2.8 (± 1.5)	-1.5 (± 1.4)		
Day 29 (Change from Baseline)	-3.1 (± 1.9)	-1.6 (± 1.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Score of The Clinical Sign Erythema at Individual Visits Compared to Baseline

End point title	Absolute Change in Score of The Clinical Sign Erythema at Individual Visits Compared to Baseline

End point description:

Erythema Score could range from 0 (no evidence) to 3 (severe) on a 7 point scale [0, 0.5, 1, 1.5, 2, 2.5, 3]. Erythema is one of three clinical scores (erythema, scaling, and infiltration) the sum of which equals the Total Clinical Score (range 0 to 9).

End point type	Secondary

End point timeframe:

4 weeks

End point values	LP0113 aerosol spray	Daivobet® gel	LEO 90100	BDP aerosol spray
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	50	50
Units: Erythema Score				
arithmetic mean (standard deviation)				
Baseline	2.3 (± 0.3)	2.3 (± 0.3)	2.3 (± 0.3)	2.3 (± 0.3)
Day 4 (Change from Baseline)	-0.4 (± 0.4)	-0.4 (± 0.5)	-0.7 (± 0.5)	-0.4 (± 0.5)
Day 8 (Change from Baseline)	-0.8 (± 0.5)	-0.8 (± 0.5)	-1.1 (± 0.5)	-0.8 (± 0.6)
Day 11 (Change from Baseline)	-1.1 (± 0.7)	-1.1 (± 0.5)	-1.4 (± 0.6)	-1.1 (± 0.6)
Day 15 (Change from Baseline)	-1.3 (± 0.6)	-1.2 (± 0.5)	-1.5 (± 0.6)	-1.2 (± 0.7)
Day 18 (Change from Baseline)	-1.5 (± 0.6)	-1.5 (± 0.6)	-1.7 (± 0.7)	-1.5 (± 0.7)
Day 22 (Change from Baseline)	-1.5 (± 0.6)	-1.4 (± 0.7)	-1.7 (± 0.6)	-1.6 (± 0.5)
Day 25 (Change from Baseline)	-1.7 (± 0.6)	-1.6 (± 0.6)	-1.9 (± 0.6)	-1.8 (± 0.5)
Day 29 (Change from Baseline)	-1.8 (± 0.6)	-1.7 (± 0.6)	-2 (± 0.5)	-1.8 (± 0.5)

End point values	Calcipotriol aerosol spray	Aerosol spray vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Erythema Score				
arithmetic mean (standard deviation)				
Baseline	2.3 (± 0.3)	2.3 (± 0.3)		
Day 4 (Change from Baseline)	-0.1 (± 0.3)	-0.2 (± 0.3)		
Day 8 (Change from Baseline)	-0.3 (± 0.4)	-0.3 (± 0.4)		
Day 11 (Change from Baseline)	-0.5 (± 0.4)	-0.3 (± 0.5)		
Day 15 (Change from Baseline)	-0.7 (± 0.5)	-0.4 (± 0.5)		
Day 18 (Change from Baseline)	-0.8 (± 0.5)	-0.5 (± 0.6)		
Day 22 (Change from Baseline)	-0.9 (± 0.5)	-0.4 (± 0.6)		
Day 25 (Change from Baseline)	-1 (± 0.5)	-0.6 (± 0.6)		
Day 29 (Change from Baseline)	-1.1 (± 0.7)	-0.6 (± 0.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Score of The Clinical Sign Scaling at Individual Visits Compared to Baseline

End point title	Absolute Change in Score of The Clinical Sign Scaling at Individual Visits Compared to Baseline

End point description:

Scaling Score could range from 0 (no evidence) to 3 (severe) on a 7 point scale [0, 0.5, 1, 1.5, 2, 2.5, 3]. Scaling is one of three clinical scores (erythema, scaling, and infiltration) the sum of which equals the Total Clinical Score (range 0 to 9).

End point type	Secondary

End point timeframe:

4 weeks

End point values	LP0113 aerosol spray	Daivobet® gel	LEO 90100	BDP aerosol spray
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	50	50
Units: Scaling Score				
arithmetic mean (standard deviation)				
Baseling	2.1 (± 0.4)	2 (± 0.4)	2 (± 0.4)	2 (± 0.4)
Day 4 (Change from Baseline)	-0.3 (± 0.5)	-0.4 (± 0.5)	-0.5 (± 0.6)	-0.2 (± 0.4)
Day 8 (Change from Baseline)	-0.9 (± 0.6)	-0.8 (± 0.6)	-1.1 (± 0.6)	-0.7 (± 0.7)
Day 11 (Change from Baseline)	-1.2 (± 0.7)	-1.1 (± 0.5)	-1.5 (± 0.6)	-1 (± 0.7)
Day 15 (Change from Baseline)	-1.5 (± 0.7)	-1.3 (± 0.6)	-1.7 (± 0.5)	-1.2 (± 0.7)
Day 18 (Change from Baseline)	-1.6 (± 0.6)	-1.5 (± 0.6)	-1.9 (± 0.5)	-1.4 (± 0.6)
Day 22 (Change from Baseline)	-1.7 (± 0.5)	-1.6 (± 0.7)	-1.9 (± 0.5)	-1.6 (± 0.6)
Day 25 (Change from Baseline)	-1.8 (± 0.5)	-1.7 (± 0.6)	-1.9 (± 0.5)	-1.7 (± 0.5)
Day 29 (Change from Baseline)	-1.8 (± 0.5)	-1.7 (± 0.6)	-2 (± 0.4)	-1.7 (± 0.5)

End point values	Calcipotriol aerosol spray	Aerosol spray vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Scaling Score				
arithmetic mean (standard deviation)				
Baseling	2 (± 0.4)	2 (± 0.4)		
Day 4 (Change from Baseline)	-0.1 (± 0.4)	-0.1 (± 0.4)		
Day 8 (Change from Baseline)	-0.3 (± 0.5)	-0.1 (± 0.5)		
Day 11 (Change from Baseline)	-0.5 (± 0.5)	-0.4 (± 0.6)		
Day 15 (Change from Baseline)	-0.7 (± 0.6)	-0.3 (± 0.5)		
Day 18 (Change from Baseline)	-0.8 (± 0.6)	-0.5 (± 0.5)		
Day 22 (Change from Baseline)	-0.9 (± 0.5)	-0.4 (± 0.6)		
Day 25 (Change from Baseline)	-1 (± 0.6)	-0.5 (± 0.6)		
Day 29 (Change from Baseline)	-1.1 (± 0.7)	-0.6 (± 0.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Score of The Clinical Sign Infiltration at Individual Visits Compared to Baseline

End point title	Absolute Change in Score of The Clinical Sign Infiltration at Individual Visits Compared to Baseline

End point description:

Infiltration Score could range from 0 (no evidence) to 3 (severe) on a 7 point scale [0, 0.5, 1, 1.5, 2, 2.5, 3]. Infiltration is one of three clinical scores (erythema, scaling, and infiltration) the sum of which equals the Total Clinical Score (range 0 to 9).

End point type	Secondary

End point timeframe:

4 weeks

End point values	LP0113 aerosol spray	Daivobet® gel	LEO 90100	BDP aerosol spray
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	50	50
Units: Infiltration Score				
arithmetic mean (standard deviation)				
Baseline	2.1 (± 0.3)	2.1 (± 0.3)	2.1 (± 0.3)	2.1 (± 0.3)
Day 4 (Change from Baseline)	-0.3 (± 0.5)	-0.2 (± 0.4)	-0.4 (± 0.5)	-0.2 (± 0.5)
Day 8 (Change from Baseline)	-0.8 (± 0.6)	-0.6 (± 0.5)	-0.9 (± 0.5)	-0.5 (± 0.5)
Day 11 (Change from Baseline)	-1.2 (± 0.7)	-0.9 (± 0.5)	-1.3 (± 0.6)	-0.9 (± 0.6)
Day 15 (Change from Baseline)	-1.5 (± 0.6)	-1.2 (± 0.7)	-1.6 (± 0.5)	-1.2 (± 0.7)
Day 18 (Change from Baseline)	-1.6 (± 0.5)	-1.4 (± 0.7)	-1.8 (± 0.5)	-1.4 (± 0.7)
Day 22 (Change from Baseline)	-1.7 (± 0.5)	-1.5 (± 0.7)	-1.9 (± 0.4)	-1.5 (± 0.6)
Day 25 (Change from Baseline)	-1.7 (± 0.5)	-1.6 (± 0.6)	-2 (± 0.3)	-1.6 (± 0.5)
Day 29 (Change from Baseline)	-1.8 (± 0.5)	-1.6 (± 0.6)	-2 (± 0.3)	-1.7 (± 0.4)

End point values	Calcipotriol aerosol spray	Aerosol spray vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Infiltration Score				
arithmetic mean (standard deviation)				
Baseline	2.1 (± 0.3)	2.1 (± 0.3)		
Day 4 (Change from Baseline)	-0.1 (± 0.4)	-0.1 (± 0.3)		
Day 8 (Change from Baseline)	-0.3 (± 0.4)	-0.1 (± 0.4)		

Day 11 (Change from Baseline)	-0.4 (± 0.5)	-0.3 (± 0.4)		
Day 15 (Change from Baseline)	-0.7 (± 0.6)	-0.3 (± 0.5)		
Day 18 (Change from Baseline)	-0.8 (± 0.6)	-0.4 (± 0.5)		
Day 22 (Change from Baseline)	-0.8 (± 0.6)	-0.3 (± 0.4)		
Day 25 (Change from Baseline)	-0.9 (± 0.6)	-0.4 (± 0.5)		
Day 29 (Change from Baseline)	-1 (± 0.7)	-0.4 (± 0.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Total Skin Thickness at End of Treatment Compared to Baseline

End point title	Absolute Change in Total Skin Thickness at End of Treatment Compared to Baseline

End point description:

The skin thickness of each test site was measured at Baseline and Day 29 using an ultrasound scanner. Data were analysed with a special software (Dermavision 2D, Cortex Technology).

Compared to non-psoriatic skin, the ultrasound image of a psoriatic plaque is characterized by an increased skin thickness and by the presence of a so-called echo-poor band just below the skin surface. The thickness of this echo-poor band is an indication of the degree of acanthosis, papillomatosis and infiltration in the upper dermis.

Three scans were recorded per test site at each time point. At the end of the trial, these images were analysed by a blinded assessor at the trial site who recorded the following for each image:
- Total skin thickness (in millimetres)
- Echo-poor band thickness (in millimetres)

Treatment differences were tested as contrasts using a two-way ANOVA with treatment and subject as fixed effects.

End point type	Secondary

End point timeframe:

4 weeks

End point values	LP0113 aerosol spray	Daivobet® gel	LEO 90100	BDP aerosol spray
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	50	50
Units: millimeters (mm)				
arithmetic mean (standard deviation)				
Baseline	2.4 (± 0.4)	2.4 (± 0.4)	2.4 (± 0.5)	2.4 (± 0.4)
Day 29 (Change from Baseline)	-1 (± 0.4)	-0.9 (± 0.4)	-1 (± 0.4)	-1 (± 0.3)

End point values	Calcipotriol aerosol spray	Aerosol spray vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: millimeters (mm)				

arithmetic mean (standard deviation)				
Baseline	2.4 (± 0.4)	2.4 (± 0.4)		
Day 29 (Change from Baseline)	-0.5 (± 0.5)	-0.2 (± 0.4)		

Statistical analyses

Statistical analysis title	Skin Thickness comparison LP0113 vs Vehicle

Statistical analysis description:

Between treatment difference in absolute change in total skin thickness from baseline to end of treatment (LP0113 aerosol spray - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	LP0113 aerosol spray v Aerosol spray vehicle
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [28]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.95
upper limit	-0.68

Notes:

[28] - Statistically significant superiority of LP0113 aerosol spray over Aerosol spray vehicle

Statistical analysis title	Skin Thickness comparison Daivobet vs Vehicle

Statistical analysis description:

Between treatment difference in absolute change in total skin thickness from baseline to end of treatment (Daivobet® gel - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v Daivobet® gel
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [29]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.88
upper limit	-0.61

Notes:

[29] - Statistically significant superiority of Daivobet® gel over Aerosol spray vehicle

Statistical analysis title	Skin Thickness comparison LEO 90100 vs Vehicle

Statistical analysis description:

Between treatment difference in absolute change in total skin thickness from baseline to end of treatment (LEO 90100 - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v LEO 90100
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [30]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.02
upper limit	-0.75

Notes:

[30] - Statistically significant superiority of LEO 90100 over Aerosol spray vehicle

Statistical analysis title	Skin Thickness comparison BDP vs Vehicle

Statistical analysis description:

Between treatment difference in absolute change in total skin thickness from baseline to end of treatment (BDP aerosol spray - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v BDP aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [31]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.95
upper limit	-0.68

Notes:

[31] - Statistically significant superiority of BDP aerosol spray over Aerosol spray vehicle

Statistical analysis title	Skin Thickness comparison Calcipotriol vs Vehicle

Statistical analysis description:

Between treatment difference in absolute change in total skin thickness from baseline to end of treatment (Calcipotriol aerosol spray - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v Calcipotriol aerosol spray

Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [32]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.46
upper limit	-0.19

Notes:

[32] - Statistically significant superiority of Calcipotriol aerosol spray over Aerosol spray vehicle

Statistical analysis title	Skin Thickness comparison LP0113 vs Calcipotriol

Statistical analysis description:

Between treatment difference in absolute change in total skin thickness from baseline to end of treatment (LP0113 aerosol spray - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v LP0113 aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [33]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.62
upper limit	-0.35

Notes:

[33] - Statistically significant superiority of LP0113 aerosol spray over Calcipotriol aerosol spray

Statistical analysis title	Skin Thickness comparison Daivobet vs Calcipotriol

Statistical analysis description:

Between treatment difference in absolute change in total skin thickness from baseline to end of treatment (Daivobet® gel - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v Daivobet® gel
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [34]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.41

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.55
upper limit	-0.28

Notes:

[34] - Statistically significant superiority of Daivobet® gel over Calcipotriol aerosol spray

Statistical analysis title	Skin Thickness comparison LEO90100 vs Calcipotriol

Statistical analysis description:

Between treatment difference in absolute change in total skin thickness from baseline to end of treatment (LEO 90100 - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v LEO 90100
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [35]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.69
upper limit	-0.42

Notes:

[35] - Statistically significant superiority of LEO 90100 over Calcipotriol aerosol spray

Statistical analysis title	Skin Thickness comparison BDP vs Calcipotriol

Statistical analysis description:

Between treatment difference in absolute change in total skin thickness from baseline to end of treatment (BDP aerosol spray - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v BDP aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [36]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.62
upper limit	-0.35

Notes:

[36] - Statistically significant superiority of BDP aerosol spray over Calcipotriol aerosol spray

Statistical analysis title	Skin Thickness comparison LP0113 vs BDP

Statistical analysis description:

Between treatment difference in absolute change in total skin thickness from baseline to end of treatment (LP0113 aerosol spray - BDP aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	BDP aerosol spray v LP0113 aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.95
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.14
upper limit	0.13

Statistical analysis title	Skin Thickness comparison Daivobet vs BDP

Statistical analysis description:

Between treatment difference in absolute change in total skin thickness from baseline to end of treatment (Daivobet® gel - BDP aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	BDP aerosol spray v Daivobet® gel
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.32
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.07
upper limit	0.2

Statistical analysis title	Skin Thickness comparison LEO 90100 vs BDP

Statistical analysis description:

Between treatment difference in absolute change in total skin thickness from baseline to end of treatment (LEO 90100 - BDP aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	BDP aerosol spray v LEO 90100

Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.32
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.07

Statistical analysis title	Skin Thickness comparison LP0113 vs LEO 90100

Statistical analysis description:

Between treatment difference in absolute change in total skin thickness from baseline to end of treatment (LP0113 aerosol spray - LEO 90100).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	LEO 90100 v LP0113 aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.35
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.07
upper limit	0.2

Statistical analysis title	Skin Thickness comparison Daivobet vs LEO 90100

Statistical analysis description:

Between treatment difference in absolute change in total skin thickness from baseline to end of treatment (Daivobet® gel - LEO 90100).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	LEO 90100 v Daivobet® gel
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.047 [37]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	0.14

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0.27

Notes:

[37] - Statistically significant superiority of LEO 90100 over Daivobet® gel

Statistical analysis title	Skin Thickness comparison LP0113 vs Daivobet

Statistical analysis description:

Between treatment difference in absolute change in total skin thickness from baseline to end of treatment (LP0113 aerosol spray - Daivobet® gel).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Daivobet® gel v LP0113 aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.29
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.21
upper limit	0.06

Secondary: Absolute Change in Echo-poor Band Thickness at End of Treatment Compared to Baseline

End point title	Absolute Change in Echo-poor Band Thickness at End of Treatment Compared to Baseline

End point description:

The skin thickness of each test site was measured at Baseline and Day 29 using an ultrasound scanner. Data were analysed with a special software (Dermavision 2D, Cortex Technology).

Compared to non-psoriatic skin, the ultrasound image of a psoriatic plaque is characterized by an increased skin thickness and by the presence of a so-called echo-poor band just below the skin surface. The thickness of this echo-poor band is an indication of the degree of acanthosis, papillomatosis and infiltration in the upper dermis.

Three scans were recorded per test site at each time point. At the end of the trial, these images were analysed by a blinded assessor at the trial site who recorded the following for each image:
- Total skin thickness (in millimetres)
- Echo-poor band thickness (in millimetres)

Treatment differences were tested as contrasts using a two-way ANOVA with treatment and subject as fixed effects.

End point type	Secondary

End point timeframe:

4 weeks

End point values	LP0113 aerosol spray	Daivobet® gel	LEO 90100	BDP aerosol spray
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	50	50
Units: millimeters (mm)				
arithmetic mean (standard deviation)				
Baseline	1.2 (± 0.5)	1.2 (± 0.5)	1.2 (± 0.6)	1.2 (± 0.4)
Day 29 (Change from Baseline)	-1.1 (± 0.4)	-1 (± 0.6)	-1.1 (± 0.5)	-1 (± 0.4)

End point values	Calcipotriol aerosol spray	Aerosol spray vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: millimeters (mm)				
arithmetic mean (standard deviation)				
Baseline	1.1 (± 0.5)	1.2 (± 0.5)		
Day 29 (Change from Baseline)	-0.5 (± 0.6)	-0.2 (± 0.6)		

Statistical analyses

Statistical analysis title	Echo-poor Band comparison LP0113 vs. Vehicle

Statistical analysis description:

Between treatment difference in absolute change in Echo-poor band thickness from baseline to end of treatment (LP0113 aerosol spray - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	LP0113 aerosol spray v Aerosol spray vehicle
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [38]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.03
upper limit	-0.68

Notes:

[38] - Statistically significant superiority of LP0113 aerosol spray over Aerosol spray vehicle

Statistical analysis title	Echo-poor Band comparison Daivobet vs. Vehicle

Statistical analysis description:

Between treatment difference in absolute change in Echo-poor band thickness from baseline to end of treatment (Daivobet® gel - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v Daivobet® gel
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [39]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.94
upper limit	-0.59

Notes:

[39] - Statistically significant superiority of Daivobet® gel over Aerosol spray vehicle

Statistical analysis title	Echo-poor Band comparison LEO 90100 vs Vehicle

Statistical analysis description:

Between treatment difference in absolute change in Echo-poor band thickness from baseline to end of treatment (LEO 90100 - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v LEO 90100
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [40]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.09
upper limit	-0.74

Notes:

[40] - Statistically significant superiority of LEO 90100 over Aerosol spray vehicle

Statistical analysis title	Echo-poor Band comparison BDP vs Vehicle

Statistical analysis description:

Between treatment difference in absolute change in Echo-poor band thickness from baseline to end of treatment (BDP aerosol spray - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v BDP aerosol spray

Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [41]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.99
upper limit	-0.64

Notes:

[41] - Statistically significant superiority of BDP aerosol spray over Aerosol spray vehicle

Statistical analysis title	Echo-poor Band comparison Calcipotriol vs Vehicle

Statistical analysis description:

Between treatment difference in absolute change in Echo-poor band thickness from baseline to end of treatment (Calcipotriol aerosol spray - Aerosol spray vehicle).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Aerosol spray vehicle v Calcipotriol aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [42]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.49
upper limit	-0.14

Notes:

[42] - Statistically significant superiority of Calcipotriol aerosol spray over Aerosol spray vehicle

Statistical analysis title	Echo-poor Band comparison LP0113 vs Calcipotriol

Statistical analysis description:

Between treatment difference in absolute change in Echo-poor band thickness from baseline to end of treatment (LP0113 aerosol spray - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v LP0113 aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [43]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.54

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.72
upper limit	-0.37

Notes:

[43] - Statistically significant superiority of LP0113 aerosol spray over Calcipotriol aerosol spray

Statistical analysis title	Echo-poor Band comparison Daivobet vs Calcipotriol

Statistical analysis description:

Between treatment difference in absolute change in Echo-poor band thickness from baseline to end of treatment (Daivobet® gel - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v Daivobet® gel
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [44]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.62
upper limit	-0.27

Notes:

[44] - Statistically significant superiority of Daivobet® gel over Calcipotriol aerosol spray

Statistical analysis title	Echo-poor Band comparison LEO90100 vs Calcipotriol

Statistical analysis description:

Between treatment difference in absolute change in Echo-poor band thickness from baseline to end of treatment (LEO 90100 - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v LEO 90100
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [45]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.77
upper limit	-0.43

Notes:

[45] - Statistically significant superiority of LEO 90100 over Calcipotriol aerosol spray

Statistical analysis title	Echo-poor Band comparison BDP vs Calcipotriol

Statistical analysis description:

Between treatment difference in absolute change in Echo-poor band thickness from baseline to end of treatment (BDP aerosol spray - Calcipotriol aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Calcipotriol aerosol spray v BDP aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [46]
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.67
upper limit	-0.33

Notes:

[46] - Statistically significant superiority of BDP aerosol spray over Calcipotriol aerosol spray

Statistical analysis title	Echo-poor Band comparison LP0113 vs BDP

Statistical analysis description:

Between treatment difference in absolute change in Echo-poor band thickness from baseline to end of treatment (LP0113 aerosol spray - BDP aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	LP0113 aerosol spray v BDP aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.62
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.22
upper limit	0.13

Statistical analysis title	Echo-poor Band comparison Daivobet vs BDP

Statistical analysis description:

Between treatment difference in absolute change in Echo-poor band thickness from baseline to end of treatment (Daivobet® gel - BDP aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	BDP aerosol spray v Daivobet® gel

Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.56
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.12
upper limit	0.23

Statistical analysis title	Echo-poor Band comparison LEO 90100 vs BDP

Statistical analysis description:

Between treatment difference in absolute change in Echo-poor band thickness from baseline to end of treatment (LEO 90100 - BDP aerosol spray).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	BDP aerosol spray v LEO 90100
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.26
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.27
upper limit	0.07

Statistical analysis title	Echo-poor Band comparison LP0113 vs LEO 90100

Statistical analysis description:

Between treatment difference in absolute change in Echo-poor band thickness from baseline to end of treatment (LP0113 aerosol spray - LEO 90100).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	LEO 90100 v LP0113 aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.52
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	0.06

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.12
upper limit	0.23

Statistical analysis title	Echo-poor Band comparison Daivobet vs LEO 90100

Statistical analysis description:

Between treatment difference in absolute change in Echo-poor band thickness from baseline to end of treatment (Daivobet® gel - LEO 90100).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	LEO 90100 v Daivobet® gel
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.086
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.02
upper limit	0.33

Statistical analysis title	Echo-poor Band comparison LP0113 vs Daivobet

Statistical analysis description:

Between treatment difference in absolute change in Echo-poor band thickness from baseline to end of treatment (LP0113 aerosol spray - Daivobet® gel).
Treatment comparisons using ANOVA with treatment and subject as factors. Same subjects receiving both treatments applied to different test sites.

Comparison groups	Daivobet® gel v LP0113 aerosol spray
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.28
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.27
upper limit	0.08

Adverse events

Adverse events information

Timeframe for reporting adverse events:

4 weeks

Adverse event reporting additional description:

No cutaneous AEs were observed and none of the AEs were assessed by the investigator to be related to the trial treatments. AEs are reported as one safety population for all IMP since all subjects were exposed to all IMPs at the same time. A total of 18 subjects (36.0%) experienced a total of 25 AEs after start of treatment with IMPs.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups

Reporting group title	Safety Population

Reporting group description:

Each subject was treated with the 6 products on 6 test sites (each 5 cm2) which were located within 1 to 6 stable psoriasis lesions (target plaques) on arms, legs and/or trunk. An application scheme showed which treatment should be applied to each test site. The test sites were marked with a numbered, disposable circular device, which was attached to the skin; the outline of each circular device was drawn on the skin using an indelible marker.

IMP was applied by site staff once daily 6 days a week for 4 weeks. A blinded investigator assessed test sites twice weekly for the severity of the clinical signs erythema, scaling, and infiltration.

Serious adverse events	Safety Population		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 50 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 4 %

Non-serious adverse events	Safety Population		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 50 (28.00%)		
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	4		
Migraine			

subjects affected / exposed occurrences (all)	2 / 50 (4.00%) 4		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	 2 / 50 (4.00%) 2		
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all)	 2 / 50 (4.00%) 2		
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all) Neck pain subjects affected / exposed occurrences (all)	 2 / 50 (4.00%) 2 2 / 50 (4.00%) 2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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.

None reported

Notes: