Clinical trial results:
A multicenter, randomized, double blind, parallel group, vehicle controlled, study of the safety and efficacy of calcitriol 3 mcg/g ointment applied twice daily for 8 weeks in pediatric subjects (2 to 12 years of age) with mild to moderate plaque psoriasis

Summary

EudraCT number	2014-001744-38
Trial protocol	DE BE ES HU IT
Global end of trial date	18 January 2016

Results information

Result version number	v1 (current)
This version publication date	26 March 2017
First version publication date	26 March 2017

Trial information

Trial identification

Sponsor protocol code	2RD.06.SPR.18132

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02186665
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GALDERMA R&D, LLC
Sponsor organisation address	5 Cedar Brook Drive Suite 1, Cranburry, United States,
Public contact	CTA Coordinator, GALDERMA R&D, SNC, +33 (0)493-95-70-85, cta.coordinator@galderma.com
Scientific contact	CTA Coordinator, GALDERMA R&D, SNC, +33 (0)493-95-70-85, cta.coordinator@galderma.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	05 December 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 January 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the safety of up to 8 weeks of treatment with calcitriol 3 mcg/g ointment versus its vehicle, when used twice daily, without occlusion, to treat children aged 2 to 12 years, with plaque psoriasis (excluding the face and scalp).

To evaluate the effect of twice daily use of calcitriol 3 mcg/g ointment versus vehicle on calcium metabolism in children aged 2 to 12 years with plaque psoriasis (excluding face and scalp).

To compare the efficacy of up to 8 weeks of treatment with calcitriol 3 mcg/g ointment versus its vehicle, when used twice daily, without occlusion, to treat children aged 2 to 12 years, with plaque psoriasis (excluding face and scalp).

Protection of trial subjects:

All study participants were required to read and sign an informed consent.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 July 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	United States: 9
Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	Belgium: 3
Country: Number of subjects enrolled	Hungary: 3
Country: Number of subjects enrolled	Italy: 1
Worldwide total number of subjects	19
EEA total number of subjects	9

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)	16
Adolescents (12-17 years)	3
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 29 subjects were screened and 19 were randomized in 13 sites in US, Canada and Europe.

Pre-assignment

Screening details:

A total of 29 subjects were screened and 19 were randomized. All subjects were treated with either calcitriol ointment or its vehicle.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Calcitriol ointment

Arm description:

calcitriol 3mcg/g ointment

Arm type	Experimental
Investigational medicinal product name	calcitriol 3mcg/g ointment
Investigational medicinal product code	CD2027
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Cutaneous use

Dosage and administration details:

Twice daily application (morning and evening) on psoriatic skin during 8 weeks

Arm title	placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	vehicle ointment
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Cutaneous use

Dosage and administration details:

Twice daily application (morning and evening) on psoriatic skin during 8 weeks

Number of subjects in period 1	Calcitriol ointment	placebo
Started	8	11
Completed	8	10
Not completed	0	1
Consent withdrawn by subject	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Calcitriol ointment
Reporting group description: calcitriol 3mcg/g ointment	
Reporting group title	placebo
Reporting group description: -	

Reporting group values	Calcitriol ointment	placebo	Total
Number of subjects	8	11	19
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	7	9	16
Adolescents (12-17 years)	1	2	3
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	9.6	9.8	
standard deviation	± 1.8	± 1.8	-
Gender categorical Units: Subjects			
Female	5	7	12
Male	3	4	7

End points

End points reporting groups

Reporting group title	Calcitriol ointment
Reporting group description: calcitriol 3mcg/g ointment	
Reporting group title	placebo
Reporting group description: -	

Primary: Success of Investigator's Global Assessment (IGA)

End point title	Success of Investigator's Global Assessment (IGA)
End point description: The number of subjects with a minimum improvement of 2 grades from baseline in the IGA score and a severity rating of 0 (clear) or 1 (almost clear) at Week 8 (LOCF)	
End point type	Primary
End point timeframe: Baseline to week 8	

End point values	Calcitriol ointment	placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	11		
Units: participants	3	7		

Statistical analyses

Statistical analysis title	Intent to treat-Week 8-LOCF
Statistical analysis description: Success rate at Week 8 (ITT, LOCF) was analyzed as primary analysis. Success rate= % of subjects with an IGA of 0 (clear) or 1 (almost clear), and at least a 2 grade improvement from baseline. ITT population: All randomized subjects to whom study medication is dispensed	
Comparison groups	Calcitriol ointment v placebo
Number of subjects included in analysis	19
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.37 [1]
Method	Fisher exact

Notes:

[1] - P-value is based on Fisher's exact test.

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 16 weeks	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	15

Reporting groups	
Reporting group title	Calcitriol ointment
Reporting group description: calcitriol 3mcg/g ointment	
Reporting group title	placebo
Reporting group description: -	

Serious adverse events	Calcitriol ointment	placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)	0 / 11 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Calcitriol ointment	placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 8 (75.00%)	8 / 11 (72.73%)	
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	2	
Urine calcium/creatinine ratio increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Arthropod bite			

subjects affected / exposed	0 / 8 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Diarrhoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 11 (0.00%)	
occurrences (all)	2	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 8 (0.00%)	2 / 11 (18.18%)	
occurrences (all)	0	2	
Oropharyngeal pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Psoriasis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Skin irritation			
subjects affected / exposed	2 / 8 (25.00%)	0 / 11 (0.00%)	
occurrences (all)	2	0	
Renal and urinary disorders			
Hypercalciuria			
subjects affected / exposed	0 / 8 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Infections and infestations			

Conjunctivitis bacterial			
subjects affected / exposed	1 / 8 (12.50%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Gastroenteritis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Laryngitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Lice infestation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Molluscum contagiosum			
subjects affected / exposed	1 / 8 (12.50%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Nasopharyngitis			
subjects affected / exposed	0 / 8 (0.00%)	2 / 11 (18.18%)	
occurrences (all)	0	4	
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Viral infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	

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.

Study was closed early due to slow enrollment

Notes: