Clinical trial results:
Calcipotriol zur Prävention der Polymorphen Lichtdermatose

Summary

EudraCT number	2008-000626-39
Trial protocol	AT
Global end of trial date	14 October 2010

Results information

Result version number	v1 (current)
This version publication date	17 October 2019
First version publication date	17 October 2019

Trial information

Trial identification

Sponsor protocol code	Calcipotriol_PLD_1.0

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Graz
Sponsor organisation address	Auenbruggerplatz 8, Graz, Austria, 8036
Public contact	Clinical Trial information, Medical University of Graz, peter.wolf@medunigraz.at
Scientific contact	Clinical Trial information, Medical University of Graz, peter.wolf@medunigraz.at

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	11 February 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 May 2009
Global end of trial reached?	Yes
Global end of trial date	14 October 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the efficacy of a pretreatment with calcipotriol in polymorphic light eruption.

Protection of trial subjects:

The study was approved by the local Ethics Committee and was conducted according to the principles of Good Clinical Practice.
Patients were subjected to Standard photo testing, as applied in daily Routine practice.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 February 2009
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	Austria: 13
Worldwide total number of subjects	13
EEA total number of subjects	13

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)	12
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment started in February 2009 and was terminated in May 2009.

Pre-assignment

Screening details:

26 patients were pre-screened.
15 patients provided Informed Consent. Of these, 13 patients were subjected to Treatment (half-side Treatment).

Period 1

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

Arms

Arm title	Half-side treatment

Arm description:

13 Patients were treated with Calcipotriol on one body side and Placebo on the other Body site.
The intra- individual Body site to be treated was determined by randomization.

Arm type	Experimental
Investigational medicinal product name	Calcipotriol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

Calcipotriol was administered twice daily for seven days before the start of photo provocation.

Number of subjects in period 1	Half-side treatment
Started	13
Completed	13

Baseline characteristics

Reporting groups	
Reporting group title	Half-side treatment
Reporting group description:	
13 Patients were treated with Calcipotriol on one body side and Placebo on the other Body site. The intra- individual Body site to be treated was determined by randomization.	

Reporting group values	Half-side treatment	Total	
Number of subjects	13	13	
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)	12	12	
From 65-84 years	1	1	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	10	10	
Male	3	3	

Subject analysis sets	
Subject analysis set title	Before photo testing
Subject analysis set type	Per protocol
Subject analysis set description:	
Before photo testing	
Subject analysis set title	After photo testing
Subject analysis set type	Per protocol
Subject analysis set description:	
After photo testing	

Reporting group values	Before photo testing	After photo testing	
Number of subjects	13	13	
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)	12	12	
From 65-84 years	1	1	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	10	10	
Male	3	3	

End points

End points reporting groups

Reporting group title	Half-side treatment
Reporting group description:	
13 Patients were treated with Calcipotriol on one body side and Placebo on the other Body site. The intra- individual Body site to be treated was determined by randomization.	
Subject analysis set title	Before photo testing
Subject analysis set type	Per protocol
Subject analysis set description:	
Before photo testing	
Subject analysis set title	After photo testing
Subject analysis set type	Per protocol
Subject analysis set description:	
After photo testing	

Primary: Polymorphic light eruption score

End point title	Polymorphic light eruption score
End point description:	
End point type	Primary
End point timeframe:	
0-144 hours	

End point values	Half-side treatment	Before photo testing	After photo testing	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	13	13	13	
Units: Units on a score	13	13	13	

Statistical analyses

Statistical analysis title	PLE score
Comparison groups	Before photo testing v After photo testing
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Mean difference (final values)
Point estimate	50
Confidence interval	
level	95 %
sides	2-sided
lower limit	5
upper limit	95

Variability estimate	Standard deviation

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

From enrolment to last visit per patient

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	Half-side treatment

Reporting group description:

13 Patients were treated with Calcipotriol on one body side and Placebo on the other Body site.
The intra- individual Body site to be treated was determined by randomization.

Serious adverse events	Half-side treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Half-side treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)		

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: As expected, photo provocation did lead to occurrence of symptoms in 12 out of 13 patients.
The occurrence of Symptoms in a circumscribed UV- exposed Body site is aim of the procedure and desired to quantify severity of disease.
Therefore such symptoms cannot be considered as Adverse Events.

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

None reported