



## Clinical trial results:

### Vitamin D supplementation in polymorphic light eruption: Randomized double-blinded placebo-controlled trial

#### Summary

EudraCT number	2012-000300-15
Trial protocol	AT
Global end of trial date	27 May 2015

#### Results information

Result version number	v1 (current)
This version publication date	04 October 2019
First version publication date	04 October 2019

#### Trial information

##### Trial identification

Sponsor protocol code	VitD_PLE_2012
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01595893
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	Medical University of Graz
Sponsor organisation address	Auenbruggerplatz 8, Graz, Austria, 8036
Public contact	Information Klinische Studie, Medical University of Graz, 43 316385 12538, dermatologie@medunigraz.at
Scientific contact	Information Klinische Studie, Medical University of Graz, Univ. Klinik Dermatologie, 43 316385 12538, dermatologie@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:

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**Results analysis stage**

Analysis stage	Final
Date of interim/final analysis	24 October 2015
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	27 May 2015
Was the trial ended prematurely?	Yes

Notes:

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**General information about the trial**

Main objective of the trial:

To determine whether oral vitamin D supplementation abrogates the pathogenic mechanisms in PLE and prevents the manifestation of the disease.

Protection of trial subjects:

The study did not contain any painful and stressful procedures and thus no specific measures had to be put in place to protect trial subjects, in particular for example measures to minimise pain and distress.

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Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 March 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

Country: Number of subjects enrolled	Austria: 26
Worldwide total number of subjects	26
EEA total number of subjects	26

Notes:

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**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)	24
From 65 to 84 years	2
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

Recruitment took place at the Medical University of Graz, Department of Dermatology. All patients provided written informed consent before starting any trial specific measures.

### Pre-assignment

Screening details:

28 patients prescreened

26 patients screened and enrolled

10 patients had vitamin D levels < 30 ng/ml and thus qualified for the active study phase. One of these 10 patients dropped out before any active study procedure for personal reasons. Another patient had to be excluded due to high Parathormone Levels.

### Pre-assignment period milestones

Number of subjects started	28 <sup>[1]</sup>
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Number of subjects completed	26
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### Pre-assignment subject non-completion reasons

Reason: Number of subjects	Adverse event, non-fatal: 1
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Reason: Number of subjects	Consent withdrawn by subject: 1
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Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Twenty-eight PLE patients were pre-screened and twenty-six patients (20 females and 6 males; mean age 46 years, range 24–76) were subjected to definite screening and first study visit between January and June of 2012 to 2014, before showing any manifestation of the disease in the season of enrolment. Two prescreened patients were not enrolled in the study. One patient was diagnosed with lupus erythematosus and one patient withdrew from the trial before any study procedure was done.

### Period 1

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

Arm title	Screening
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Arm description:

The clinical trial was prematurely terminated after 26 patients had been screened, since it became evident that the majority of patients had 25(OH)D serum levels above 30 ng ml<sup>-1</sup> and addressing the original study hypothesis (that oral vitamin D supplementation does protect against PLE) was neither reachable within a proper time frame nor appropriate and thus this analysis was not executed.

Arm type	Screening
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Investigational medicinal product name	Vitamine D3
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Investigational medicinal product code	
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Other name	Oleovit D3
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Pharmaceutical forms	Oral drops
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Routes of administration	Oral use
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Dosage and administration details:

40,000 IE vitamin D3 per 70 kg body weight, given twice (2 weeks apart)

<b>Number of subjects in period 1</b>	Screening
Started	26
Completed	26

## Baseline characteristics

### Reporting groups

Reporting group title	Overall trial
Reporting group description: -	

Reporting group values	Overall trial	Total	
Number of subjects	26	26	
Age categorical			
28 patients prescreened 26 patients screened and enrolled 10 patients had vitamin D levels < 30 ng/ml and thus qualified for the active study phase One of these 10 patients dropped out before any active study procedure for personal reasons Another patient had to be excluded due to high Parathormone levels  Thus, together, only 8 patients reached the active study phase: 5 received placebo 3 received Vitamin D			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Twenty-eight PLE patients were pre-screened and twenty-six patients (20 females and 6 males; mean age 46 years, range 24–76) were subjected to definite screening and first study visit between January and June of 2012 to 2014, before showing any manifestation of the disease in the season of enrolment.			
Units: years			
arithmetic mean	46		
full range (min-max)	24 to 76	-	
Gender categorical			
Units: Subjects			
Female	20	20	
Male	6	6	

### Subject analysis sets

Subject analysis set title	Treg numbers
Subject analysis set type	Intention-to-treat

Subject analysis set description:

The clinical trial was prematurely terminated after 26 patients had been screened, since it became evident that the majority of patients had 25(OH)D serum levels above 30 ng ml<sup>-1</sup> and addressing the original study hypothesis (that oral vitamin D supplementation does protect against PLE) was neither reachable within a proper time frame nor appropriate and thus this analysis was not executed. The analysis of this report therefore focuses on investigating a possible influence of season on baseline Treg numbers, Treg function and vitamin D serum levels in 26 PLE patients at the time point of first study

visit (TP1), taking place in the period spanning from January to June, whereas the other time points were omitted from the present analysis. Grouping of patients at TP1 in two periods, the winter period for those recruited from day 10 to 42 and the spring/early summer period for those recruited from day 108 to 176, allowed comparison of Treg numbers and function with respect to the season.

Reporting group values	Treg numbers		
Number of subjects	26		
Age categorical			
<p>28 patients prescreened  26 patients screened and enrolled  10 patients had vitamin D levels &lt; 30 ng/ml and thus qualified for the active study phase One of these 10 patients dropped out before any active study procedure for personal reasons Another patient had to be excluded due to high Parathormone levels</p> <p>Thus, together, only 8 patients reached the active study phase:  5 received placebo  3 received Vitamin D</p>			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous			
<p>Twenty-eight PLE patients were pre-screened and twenty-six patients (20 females and 6 males; mean age 46 years, range 24-76) were subjected to definite screening and first study visit between January and June of 2012 to 2014, before showing any manifestation of the disease in the season of enrolment.</p>			
Units: years			
arithmetic mean full range (min-max)			
Gender categorical			
Units: Subjects			
Female	20		
Male	6		

## End points

### End points reporting groups

Reporting group title	Screening
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Reporting group description:

The clinical trial was prematurely terminated after 26 patients had been screened, since it became evident that the majority of patients had 25(OH)D serum levels above 30 ng ml<sup>-1</sup> and addressing the original study hypothesis (that oral vitamin D supplementation does protect against PLE) was neither reachable within a proper time frame nor appropriate and thus this analysis was not executed.

Subject analysis set title	Treg numbers
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Subject analysis set description:

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### Primary: Effect of Vitamin D to protect from clinical manifestation of PLE

End point title	Effect of Vitamin D to protect from clinical manifestation of
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End point description:

None of the predefined end points were analysed since the recruitment rate was insufficient and the study was therefore prematurely terminated.

End point type	Primary
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End point timeframe:

within 144 hours

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The study was prematurely terminated. Predefined end points were not analysed.

End point values	Screening			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Units on a score	26			

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

2012/04 - 2015/05/31

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	c
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### Reporting groups

Reporting group title	Active study phase
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Reporting group description:

26 patients screened and enrolled

10 patients had vitamin D levels < 30 ng/ml and thus qualified for the active study Phase. One of these 10 patients dropped out before any active study procedure for personal reasons Another patient had to be excluded due to high Parathormone levels

Serious adverse events	Active study phase		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (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	Active study phase		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 8 (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: 26 patients screened and enrolled

10 patients had vitamin D levels < 30 ng/ml and thus qualified for the active study Phase. One of these 10 patients dropped out before any active study procedure for personal reasons Another patient had to be excluded due to high Parathormone Levels.

The clinical trial was prematurely terminated after 26 patients had been screened. The majority of screened patients did not meet the main inclusion criterion which was a 25(OH)D serum level below 30 ng ml<sup>-1</sup>.



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### 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.

The clinical trial was prematurely terminated after 26 patients had been screened, since it became evident that the majority of patients had 25(OH)D serum levels above 30 ng ml <sup>-1</sup> , addressing the study hypothesis was neither reachable nor appropriate
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Notes:

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/26911519>