Clinical trial results:
Die Bedeutung des sensorischen Nervensystems für die Repigmentierung der Haut bei Vitiligo

(engl.: The role of the sensory nervous system for repigmentation in vitiligo)

Summary

EudraCT number	2006-000838-12
Trial protocol	AT
Global end of trial date	05 March 2008

Results information

Result version number	v1 (current)
This version publication date	05 October 2019
First version publication date	05 October 2019

Trial information

Trial identification

Sponsor protocol code	Vit-Caps-Protocol-V1.0

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medizinische Universität Graz
Sponsor organisation address	Auenbruggerplatz 8, Graz, Austria, 8036
Public contact	Prof. Franz Legat, Medizinische Universität Graz, 0043 31638580543, franz.legat@medunigraz.at
Scientific contact	Prof. Franz Legat, Medizinische Universität Graz, 0043 31638580543, franz.legat@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	05 March 2008
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 March 2008
Global end of trial reached?	Yes
Global end of trial date	05 March 2008
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To test whether repeated stimulation of the skin's sensory nervous system via cutaneous application of a capsaicin-containing cream affects the repigmentation of vitiliginous skin areas

Protection of trial subjects:

The study was approved by the local Ethics Committee.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 May 2006
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: 7
Worldwide total number of subjects	7
EEA total number of subjects	7

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)	7
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

7 patients were recruited for the study.
Recruitment was teminated early in January 2007, since none of the included patients reached clinical repigmentation of vitiligo.

Pre-assignment

Screening details:

There were no screening failures in this Trial.

Period 1

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

Arms

Arm title	Half-side treatment

Arm description:

Half-side Treatment study.
All Patients were treated on lesional Skin on one Body site with Capsaicin containing cream.
On the other Body site Vehicle cream was used.

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

Dosage and administration details:

Capsaicin 0,05% cream (in Diprosicc) versus Diprosicc three times/week (Monday, Wednesday, Friday) for a duration of 12 weeks, a total of 36 treatments.
There was also the option of a Treatment Prolongation for another 12 weeks.

Number of subjects in period 1	Half-side treatment
Started	7
Completed	5
Not completed	2
Consent withdrawn by subject	1
Adverse event, non-fatal	1

Baseline characteristics

Reporting groups	
Reporting group title	Half-side treatment

Reporting group description:

Half-side Treatment study.
All Patients were treated on lesional Skin on one Body site with Capsaicin containing cream.
On the other Body site Vehicle cream was used.

Reporting group values	Half-side treatment	Total	
Number of subjects	7	7	
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)	7	7	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	2	2	
Male	5	5	

End points

End points reporting groups

Reporting group title	Half-side treatment

Reporting group description:

Half-side Treatment study.
All Patients were treated on lesional Skin on one Body site with Capsaicin containing cream.
On the other Body site Vehicle cream was used.

Primary: Repigmentation of the skin

End point title	Repigmentation of the skin[1]

End point description:

The End Point was not analysed, since the planned recruitment number could not be reached and the study was terminated prematurely.

End point type	Primary

End point timeframe:

3 months

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: None of the predefined end points were analysed.
The study was terminated prematurely because none of the included patients showed repigmentation of vitiligo on either treatment side.

End point values	Half-side treatment			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: percent				
number (not applicable)	5			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From time of informed consent to last follow-up visit.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	From informed consent to end of follow-up

Reporting group description: -

Serious adverse events	From informed consent to end of follow-up		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (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	From informed consent to end of follow-up		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 7 (28.57%)		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Burning sensation			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	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

None reported