Clinical trial results:
Mikroperfusions-Pilotstudie zur Korrelation von Schmerzreaktion und neurogener Entzündung bei photodynamischer Therapie superfizieller Basaliome

(English: Microperfusion-pilotstudy to correlate pain and neurogenic inflammation induced by photodynamic therapy of superficial basal cell carcinomas)

Summary

EudraCT number	2005-006136-29
Trial protocol	AT
Global end of trial date	10 July 2007

Results information

Result version number	v1 (current)
This version publication date	26 October 2019
First version publication date	26 October 2019

Trial information

Trial identification

Sponsor protocol code	PDT-sBCC-MP-V1.0

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	Auenbruggerplatz 8, Medical University of Graz, peter.wolf@medunigraz.at
Scientific contact	Auenbruggerplatz 8, 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	23 February 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 July 2007
Global end of trial reached?	Yes
Global end of trial date	10 July 2007
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To test whether pretreatment of superficial basal cell carcinomas with capsaicin cream reduces neurogenic inflammation and pain during photodynamic treatment

Protection of trial subjects:

The study was approved by the local Ethics Committee and was conducted according to the principles of Good Clinical Practice.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 February 2007
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: 3
Worldwide total number of subjects	3
EEA total number of subjects	3

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)	1
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment started in February 2007.
The study was prematurely terminated in July 2007.
The reason for the early termination was that the treatment schedule of four daily treatments over two weeks wasn't accepted by the patients.

Pre-assignment

Screening details:

3 patients provided Informed Consent and received Treatment.

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: -	
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:

0,05% Capsaicin cream, administered four times daily over the Course of two weeks

Number of subjects in period 1	Half side treatment
Started	3
Completed	3

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	3	3	
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)	1	1	
From 65-84 years	2	2	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	1	1	
Male	2	2	

End points

End points reporting groups

Reporting group title	Half side treatment

Reporting group description: -

Primary: Visual Analogue Scale for Pain (VAS)

End point title	Visual Analogue Scale for Pain (VAS)[1]

End point description:

None of the predefined end Points were analysed since the study was terminated prematurely.

End point type	Primary

End point timeframe:

24 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: None of the predefined end Points were analysed since the study was terminated prematurely.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

From enrolment to informed consent

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	Capsaicin cream
Reporting group description: -	
Reporting group title	Vehicle cream
Reporting group description: -	

Serious adverse events	Capsaicin cream	Vehicle cream	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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: 5 %

Non-serious adverse events	Capsaicin cream	Vehicle cream	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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: Pain is a typical side effect of photodynamic therapy (PDT). The study was designed to reduce PDT- associated pain by pre-treatment with Capsaicin cream. Pain was an absolute prerequisite to evaluate the study end point. Therefore PDT-associated pain was not considered as Adverse Event.

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