Clinical trial results:
Open clinical study to determine the tolerability of Pyolysin®-Salbe in children aged between 0 and 17 years during the dermatological treatment of superficial wounds

Summary

EudraCT number	2011-002755-34
Trial protocol	DE
Global end of trial date	03 November 2014

Results information

Result version number	v1 (current)
This version publication date	15 May 2016
First version publication date	15 May 2016
Summary attachment (see zip file)	Synopsis SWB-06-11 (Synopsis.pdf)

Trial information

Trial identification

Sponsor protocol code	SWB-06-11

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Serumwerk Bernburg AG
Sponsor organisation address	Hallesche Landstrasse 105b, Bernburg, Germany, 06406
Public contact	Susanne Manhart, Serumwerk Bernburg AG, 0049 03471860180, smanhart@serumwerk.de
Scientific contact	Susanne Manhart, Serumwerk Bernburg AG, 0049 03471860180, smanhart@serumwerk.de

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	03 November 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 November 2014
Global end of trial reached?	Yes
Global end of trial date	03 November 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To confirm the tolerability of the Pyolysin-Salbe in the age group from 0 to 17 years

Protection of trial subjects:

The protocol and amendment were approved by local ethics committee and competent authority. The trial was conducted in accordance with good clinical practice and the Declaration of Helsinki. Informed consent was obtained in writing prior to any trial-related activities.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2012
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	Germany: 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)	3
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were screened in the period 01.03.2012 until 03.11.2014 . The trial took place in one center in Germany.
Examination of the wound and wound cleansing by physician, an overview of the wound conditions was gained and decided whether it was possible for the patient to participate in the Trial, only 3 patients of 120 planned were recruited

Pre-assignment

Screening details:

Screening of patients was performed using a screening form in selected doctors' practices

Pre-assignment period milestones

Number of subjects started	3
Number of subjects completed	3

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	Group A

Arm description:

7-17 years

Arm type	Experimental
Investigational medicinal product name	Pyolysin®-Salbe, Creme
Investigational medicinal product code	
Other name	Pyolysin ointment
Pharmaceutical forms	Ointment
Routes of administration	Cutaneous use

Dosage and administration details:

Pyolysin® ointment is applied thinly to the affected area of skin twice daily (morning and evening). The area to be treated is defined or demarcated by a template (min. size 2 x 2 cm or 4 cm2; max. 8 x 8 cm or 64 cm2). This area is marked on the skin with a skin-tolerable permanent skin marker (Viomedex) with the aid of the template. This ensures that the ointment is applied correctly to the same area every day.
The treatment is continued up to a maximum of 3 weeks until wound healing is achieved.

Number of subjects in period 1	Group A
Started	3
Completed	3

Baseline characteristics

Reporting groups	
Reporting group title	Group A
Reporting group description: 7-17 years	

Reporting group values	Group A	Total	
Number of subjects	3	3	
Age categorical Units: Subjects			
Adolescents (12-17 years)	3	3	
Gender categorical Units: Subjects			
Female	1	1	
Male	2	2	

End points

End points reporting groups

Reporting group title	Group A
Reporting group description:	
7-17 years	

Primary: Visual Score

End point title	Visual Score[1]
End point description:	
Tolerability (assessment based on clinical and subjective scores) Visual Score: 0 = geheilt, 1 = leichte Rötung der Haut, 2 = Restschorf ohne Erosion, leichte Umgebungsrötung, 3 = Hauterosion, leichte Umgebungsentzündung, 4 = Hauterosion, Nässen, starke Umgebungsentzündung,	
End point type	Primary
End point timeframe:	
Visit 0 (Day 0), Visit 1 (week 1), Visit 2 (week 2), Visit 3 (week 3 or end)	
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 planned methods of statistical Analysis could not be used because of the small number of 3 cases.	

End point values	Group A			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: 0, 1, 2, 3, 4				
arithmetic mean (standard deviation)				
visit 0	3.33 (± 0.58)			
visit 1	1.33 (± 1.53)			
visit 2	0 (± 0)			

Statistical analyses

No statistical analyses for this end point

Primary: SCORAD intensity of wound

End point title	SCORAD intensity of wound[2]
End point description:	
Tolerability (assessment based on clinical and subjective scores) SCORAD: 0 = keine, 1 = leicht, 2 = mäßig, 3 = stark	
End point type	Primary
End point timeframe:	
Visit 0 (Day 0), Visit 1 (week 1), Visit 2 (week2), visit 3 (week 3)	

Notes:

[2] - 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 planned methods of statistical Analysis could not be used because of the small number of 3 cases.

End point values	Group A			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: 0, 1, 2, 3				
arithmetic mean (standard deviation)				
Visit 0	2.33 (± 0.57)			
Visit 1	1.3 (± 1.57)			
Visit 2	0 (± 0)			

Statistical analyses

No statistical analyses for this end point

Secondary: wound size

End point title	wound size

End point description:

area of wound in cm2, additional information concerning the progress of wound healing

End point type	Secondary

End point timeframe:

Visit 0 (Day 0), Visit 1 (week 1), Visit 2 (week 2), Visit 3 (week 3)

End point values	Group A			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: cm2				
arithmetic mean (standard deviation)				
Visit 0	2.67 (± 1.15)			
Visit 1	2.67 (± 1.15)			
Visit 2	0 (± 0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Skin temperature wound

End point title	Skin temperature wound

End point description:

measurement of skin temperature of the wound, additional information concerning the progress of

wound healing

End point type	Secondary

End point timeframe:

Visit 0 (Day 0), Visit 1 (week 1), Visit 2 (week 2), Visit 3 (week 3)

End point values	Group A			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: °C				
arithmetic mean (standard deviation)				
Visit 0	28.5 (± 0.7)			
Visit 1	27.47 (± 0.49)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

3 patients received Pyolysin ointment thinly to the affected area of skin twice daily (morning and evening). Treatment Duration was 7, 10 and 14 days, respectively. No adverse Events have been observed.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16

Reporting groups

Reporting group title	Group A (7-17 years)

Reporting group description:

3 patients

Serious adverse events	Group A (7-17 years)		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Group A (7-17 years)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	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: due to insufficient recruitment only 3 patients were treated, there were no non-serious adverse events observed during this trial

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 December 2013	amendment to the protocol, adaptation of the inclusion criteria, changes in Informed Consent form and CRF, Extension of the duration of the trial due to insufficient recruitment (3 patients of 120)

Notes:

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.

Due to insufficient recruitment only 3 patients were treated.

Notes: