

**Clinical trial results:****Clinical trial on skin care in Neonatology. A comparison between two skin care products and no skin care****Summary**

EudraCT number	2005-001269-32
Trial protocol	AT
Global end of trial date	28 February 2007

Results information

Result version number	v1 (current)
This version publication date	24 October 2021
First version publication date	24 October 2021

Trial information**Trial identification**

Sponsor protocol code	01/05
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University Innsbruck
Sponsor organisation address	Christoph-Probst-Platz 1, Innrain 52, Innsbruck, Austria, 6020
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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	28 February 2007
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 February 2007
Global end of trial reached?	Yes
Global end of trial date	28 February 2007
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Comparison of the effect of 2 skin care products and no skin care on the integrity and condition of skin in newborn infants.

Protection of trial subjects:

Infants, who developed dermatitis were treated with standard of care topical skin therapy. These neonates were switched to a therapy regime with ultrasic / ultrabas.

Background therapy:

Subjects received treatment of an intensive care unit.

Evidence for comparator:

There was no evidence for a comparator.

Actual start date of recruitment	01 October 2004
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: 173
Worldwide total number of subjects	173
EEA total number of subjects	173

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	173
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 to 84 years	0

Subject disposition

Recruitment

Recruitment details:

Between October 2004 and November 2006, all infants between 25 and 36 weeks of gestation who were admitted to a neonatal intensive care unit (NICU) were prospectively enrolled.

Pre-assignment

Screening details:

Infants were excluded if survival was expected to be <48 hours, or if they had manifest skin disease or life-threatening congenital anomalies.

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

Once informed consent was obtained, neonates were randomly assigned to group A (Bepanthen®; Bayer Healthcare, Wuppertal, Germany), group B (olive oil cream), or group C (control).

Arms

Are arms mutually exclusive?	Yes
Arm title	Bepanthen

Arm description:

Skin therapy was applied twice a day. The body, except the face and scalp, was treated with a thin coat of the Bepanthen cream. In this treatment group, therapy commenced within the first 24 hours of life.

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

Dosage and administration details:

Topical emollient was dispensed to each neonate in tubes containing 10 g that contained enough emollient for 1 day. Each neonate was continuously treated for a maximum of 4 weeks. Infants who were transferred out of the NICU before day 28 were followed up on the intermediate care unit. Skin therapy was applied twice a day. The body, except the face and scalp, was treated with a thin coat of the Bepanthen cream.

Arm title	Olive Oil Cream
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Arm description:

Skin therapy was applied twice a day. The body, except the face and scalp, was treated with olive oil cream. In this treatment group, therapy commenced within the first 24 hours of life.

Arm type	Experimental
Investigational medicinal product name	Lanoline/ Olive Oil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

In the current study a mixture of 30% olive oil and 70% lanoline produced in our pharmacy was used. Each neonate was continuously treated for a maximum of 4 weeks. Infants who were transferred out of the NICU before day 28 were followed up on the intermediate care unit. Skin therapy was applied twice

a day. The body, except the face and scalp, was treated with olive oil cream.

Arm title	Control
Arm description: The control group received routine skin care without topical emollients or other measures to prevent skin breakdown or modulate skin-barrier function.	
Arm type	control
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Bepanthen	Olive Oil Cream	Control
Started	57	58	58
Completed	49	47	51
Not completed	8	11	7
Adverse event, serious fatal	1	-	-
Discharge or transfer to a different hospital	7	11	7

Baseline characteristics

Reporting groups

Reporting group title	Bepanthen
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Reporting group description:

Skin therapy was applied twice a day. The body, except the face and scalp, was treated with a thin coat of the Bepanthen cream. In this treatment group, therapy commenced within the first 24 hours of life.

Reporting group title	Olive Oil Cream
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Reporting group description:

Skin therapy was applied twice a day. The body, except the face and scalp, was treated with olive oil cream. In this treatment group, therapy commenced within the first 24 hours of life.

Reporting group title	Control
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Reporting group description:

The control group received routine skin care without topical emollients or other measures to prevent skin breakdown or modulate skin-barrier function.

Reporting group values	Bepanthen	Olive Oil Cream	Control
Number of subjects	57	58	58
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	57	58	58
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: weeks			
median	30.3	30.4	30.5
full range (min-max)	25 to 36	25 to 36	25 to 36
Gender categorical Units: Subjects			
Female	31	27	22
Male	26	31	36

Reporting group values	Total		
Number of subjects	173		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	173		
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			
Units: weeks			
median			
full range (min-max)	-		
Gender categorical			
Units: Subjects			
Female	80		
Male	93		

End points

End points reporting groups

Reporting group title	Bepanthen
Reporting group description: Skin therapy was applied twice a day. The body, except the face and scalp, was treated with a thin coat of the Bepanthen cream. In this treatment group, therapy commenced within the first 24 hours of life.	
Reporting group title	Olive Oil Cream
Reporting group description: Skin therapy was applied twice a day. The body, except the face and scalp, was treated with olive oil cream. In this treatment group, therapy commenced within the first 24 hours of life.	
Reporting group title	Control
Reporting group description: The control group received routine skin care without topical emollients or other measures to prevent skin breakdown or modulate skin-barrier function.	

Primary: Skin Condition Grading

End point title	Skin Condition Grading
End point description: Skin condition was graded on a 4-point scale (1–4) modified from the one published by Lane and Drost with a score of one denoting the best condition and a score of 4 the worst. Grading considered skin dryness, presence of erythema, and skin breakdown.	
End point type	Primary
End point timeframe: Day 0 - Day 28	

End point values	Bepanthen	Olive Oil Cream	Control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	57 ^[1]	58 ^[2]	58 ^[3]	
Units: Skin Condition Grading				
arithmetic mean (standard deviation)				
Day 0	1.07 (± 0.29)	1.10 (± 0.31)	1.10 (± 0.31)	
Day 7	1.18 (± 0.43)	1.09 (± 0.28)	1.33 (± 0.74)	
Day 14	1.67 (± 0.81)	1.28 (± 0.56)	2.11 (± 1.04)	
Day 21	2.07 (± 1.15)	1.40 (± 0.79)	3.00 (± 1.05)	
Day 28	2.00 (± 1.09)	1.40 (± 0.81)	2.70 (± 1.03)	

Notes:

[1] - Day 0:57 subjects; day 7:57 subjects; day 14:57 subjects; day 21:55 subjects; day 28:38 subjects

[2] - Day 0:58 subjects; day 7:58 subjects; day 14:58 subjects; day 21:58 subjects; day 28:45 subjects

[3] - Day 0:58 subjects; day 7:58 subjects; day 14:56 subjects; day 21:48 subjects; day 28:20 subjects

Statistical analyses

Statistical analysis title	Skin Condition Grading, Day 7
Comparison groups	Bepanthen v Olive Oil Cream v Control

Number of subjects included in analysis	173
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.042
Method	t-test, 2-sided

Statistical analysis title	Skin Condition Grading, Day 14
Comparison groups	Bepanthen v Olive Oil Cream v Control
Number of subjects included in analysis	173
Analysis specification	Pre-specified
Analysis type	equivalence ^[4]
P-value	< 0.001
Method	t-test, 2-sided

Notes:

[4] - At day 14, 171 subjects were analysed.

Statistical analysis title	Skin Condition Grading, Day 21
Comparison groups	Bepanthen v Olive Oil Cream v Control
Number of subjects included in analysis	173
Analysis specification	Pre-specified
Analysis type	equivalence ^[5]
P-value	< 0.001
Method	t-test, 2-sided

Notes:

[5] - At day 21, 161 subjects were analysed.

Statistical analysis title	Skin Condition Grading, Day 28
Comparison groups	Bepanthen v Olive Oil Cream v Control
Number of subjects included in analysis	173
Analysis specification	Pre-specified
Analysis type	equivalence ^[6]
P-value	< 0.001
Method	t-test, 2-sided

Notes:

[6] - At day 28, 103 subjects were analysed.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

October 2004 - November 2006

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	3.0
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Reporting groups

Reporting group title	Bepanthen
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Reporting group description:

Skin therapy was applied twice a day. The body, except the face and scalp, was treated with a thin coat of the Bepanthen cream. In this treatment group, therapy commenced within the first 24 hours of life.

Reporting group title	Olive oil cream
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Reporting group description:

Skin therapy was applied twice a day. The body, except the face and scalp, was treated with olive oil cream. In this treatment group, therapy commenced within the first 24 hours of life.

Reporting group title	Control
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Reporting group description:

The control group received routine skin care without topical emollients or other measures to prevent skin breakdown or modulate skin-barrier function.

Serious adverse events	Bepanthen	Olive oil cream	Control
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 57 (0.00%)	0 / 58 (0.00%)	0 / 58 (0.00%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0

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

Non-serious adverse events	Bepanthen	Olive oil cream	Control
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 57 (19.30%)	2 / 58 (3.45%)	31 / 58 (53.45%)
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	11 / 57 (19.30%)	2 / 58 (3.45%)	31 / 58 (53.45%)
occurrences (all)	44	44	44

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

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/18429773>