



Clinical trial results: PpIX in curretted and non-curretted skin after Metvix application Summary

EudraCT number	2016-005084-14
Trial protocol	DK
Global end of trial date	31 May 2017

Results information

Result version number	v1 (current)
This version publication date	04 June 2020
First version publication date	04 June 2020

Trial information

Trial identification

Sponsor protocol code	56297
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bispebjerg Hospital
Sponsor organisation address	Bispebjerg Bakke 23, Copenhagen NV, Denmark,
Public contact	Department of Dermatology, D92, Bispebjerg hospital , hans.christian.olsen.wulf@regionh.dk
Scientific contact	Department of Dermatology, D92, Bispebjerg hospital , hans.christian.olsen.wulf@regionh.dk

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	01 December 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 May 2017
Global end of trial reached?	Yes
Global end of trial date	31 May 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To investigate how fast PpIX is produced in curretted and non-curretted skin.

Protection of trial subjects:

Not necessary

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 14
Worldwide total number of subjects	14
EEA total number of subjects	14

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)	4
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects were recruited from the Department of Dermatology, Bispebjerg Hospital

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	+cur

Arm description: -

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

Dosage and administration details:

Cutaneous use

Arm title	-cur
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Arm description: -

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

Dosage and administration details:

Cutaneous use

Number of subjects in period 1	+cur	-cur
Started	14	14
Completed	14	14

Baseline characteristics

Reporting groups

Reporting group title	Overall period
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Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	14	14	
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)	4	4	
From 65-84 years	10	10	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	74		
full range (min-max)	55 to 84	-	
Gender categorical			
Units: Subjects			
Female	2	2	
Male	12	12	

End points

End points reporting groups

Reporting group title	+cur
Reporting group description: -	
Reporting group title	-cur
Reporting group description: -	

Primary: PpIX level

End point title	PpIX level
End point description:	
End point type	Primary
End point timeframe:	
PpIX level 3 h after MAL application	

End point values	+cur	-cur		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	14		
Units: AU	22	20		

Statistical analyses

Statistical analysis title	Wilcoxon Signed Ranks Test
Statistical analysis description:	
Parred design. Only 14 subjects in this analysis. Read all about the analysis here: Heerfordt IM, Bieliauskiene G, Wulf HC. Protoporphyrin IX formation after application of methyl aminolevulinate on the face and scalp with and without prior curettage. Photodiagnosis Photodyn Ther 2018; 22: 155–157	
Comparison groups	-cur v +cur
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	equivalence ^[1]
P-value	= 0.9
Method	Wilcoxon (Mann-Whitney)

Notes:

[1] - Parred design. Only 14 subjects in this analysis.

Read all about the analysis here:

Heerfordt IM, Bieliauskiene G, Wulf HC. Protoporphyrin IX formation after application of methyl aminolevulinate on the face and scalp with and without prior curettage. Photodiagnosis Photodyn Ther 2018; 22: 155–157

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

From MAL application and 6 h ahead

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10.0
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Reporting groups

Reporting group title	+cur
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Reporting group description: -

Reporting group title	-cur
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Reporting group description: -

Serious adverse events	+cur	-cur	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	+cur	-cur	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (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: There were no non-serious adverse events.

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