



Clinical trial results: Photodynamic therapy without curettage Summary

EudraCT number	2017-001701-33
Trial protocol	DK
Global end of trial date	14 December 2017

Results information

Result version number	v1 (current)
This version publication date	02 July 2020
First version publication date	02 July 2020

Trial information

Trial identification

Sponsor protocol code	58161
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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.wulf@regionh.dk
Scientific contact	Department of Dermatology, D92, Bispebjerg Hospital, hans.christian.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	03 December 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 December 2017
Global end of trial reached?	Yes
Global end of trial date	14 December 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Investigate if photodynamic therapy without curettage is equally effective as photodynamic therapy with curettage.

Protection of trial subjects:

No special protection was needed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 June 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: 25
Worldwide total number of subjects	25
EEA total number of subjects	25

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)	2
From 65 to 84 years	20
85 years and over	3

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients were recruited from Department of Dermatology, Bispebjerg Hospital.

Period 1

Period 1 title	Baseline period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Investigator ^[1]

Blinding implementation details:

The subjects were not blinded. The treatments were performed by a non blinded investigator. The treatment efficacy evaluations were performed by a blinded investigator.

Arms

Are arms mutually exclusive?	No
Arm title	+cur

Arm description: -

Arm type	Active comparator
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

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: The subjects were not blinded. The treatments were performed by a non blinded investigator. The treatment efficacy evaluations were performed by a blinded investigator.

Number of subjects in period 1	+cur	-cur
Started	25	25
Completed	25	25

Baseline characteristics

Reporting groups

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

Reporting group values	+cur	-cur	Total
Number of subjects	25	25	25
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
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)	2	2	2
From 65-84 years	20	20	20
85 years and over	3	3	3
Gender categorical Units: Subjects			
Female	0	0	0
Male	25	25	25

End points

End points reporting groups

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

Primary: Clearance rate 3 months after treatment.

End point title	Clearance rate 3 months after treatment.
End point description:	
End point type	Primary
End point timeframe:	
Clearance rate 3 months after treatment. Number of AKs are counted immediately before treatment and 3 months after treatment	

End point values	+cur	-cur		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	25		
Units: Number	86	84		

Statistical analyses

Statistical analysis title	Paired t-test
Comparison groups	+cur v -cur
Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[1]
P-value	= 0.1
Method	t-test, 2-sided

Notes:

[1] - There are only 25 subjects in this analysis. 25 subjects in group 1. And the same 25 subjects in group 2. A paired design. Not 50 subjects.

Read our article reporting results in details: <https://doi.org/10.1111/jdv.15744>

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

3 months

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20
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Reporting groups

Reporting group title	All subjects
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Reporting group description: -

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 event found in 5% or more.

Serious adverse events	All subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 25 (20.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Gastrointestinal disorders			
Ileus	Additional description: SAE. Treatment and event is not related.		
subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fistel			
subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cancer surgery	Additional description: Rectum cancer surgery		
subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Infection	Additional description: SAE. Treatment and event is not related		
subjects affected / exposed	2 / 25 (8.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	All subjects		
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 25 (0.00%)		

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