



Clinical trial results:

Daylight-PDT in the treatment of actinic keratosis: a pilot study comparing two different light sensitizers

Summary

EudraCT number	2013-001389-40
Trial protocol	FI
Global end of trial date	11 February 2016

Results information

Result version number	v1 (current)
This version publication date	14 February 2025
First version publication date	14 February 2025
Summary attachment (see zip file)	Publication (bjd0427.pdf)

Trial information

Trial identification

Sponsor protocol code	phch2013
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02149342
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Joint Authority for Päijät-Häme Social and health care group
Sponsor organisation address	Keskussairaalankatu 7, Lahti, Finland, 15850
Public contact	Mari Grönroos, Mari Grönroos, mari.gronroos@co.inet.fi
Scientific contact	Mari Grönroos, Mari Grönroos, mari.gronroos@co.inet.fi

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	11 February 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 February 2016
Global end of trial reached?	Yes
Global end of trial date	11 February 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Comparing the histological and clinical efficacy of two light sensitizers in the daylight-PDT treatment of actinic keratosis

Protection of trial subjects:

We used a treatment protocol using daylight as a light source. This has previously been shown as painless and cause less adverse effects compared to traditional treatment with LED light

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 March 2014
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	Finland: 28
Worldwide total number of subjects	28
EEA total number of subjects	28

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)	0
From 65 to 84 years	20
85 years and over	8

Subject disposition

Recruitment

Recruitment details:

Inclusion criteria were patients with at least two actinic keratoses ≥ 6 mm in diameter symmetrically on the faces or scalp and equally clinically graded.

Pre-assignment

Screening details:

Clinical examination of the skin

Period 1

Period 1 title	Treatment (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

The randomization results (which treatment side was treated with which photosensitizer) were kept blinded from the investigators who conducted the follow-up visits, and from the pathologist and patients.

Arms

Are arms mutually exclusive?	No
Arm title	HAL arm

Arm description:

The treatments were given in a randomized, slit-face design, HAL on the other side and MAL on the other side symmetrically. In total, 14 patients were recruited and treated in a slit-face design (in total 28 treatment halves)

Arm type	Experimental
Investigational medicinal product name	HAL
Investigational medicinal product code	
Other name	hexyl-aminolaevulinate
Pharmaceutical forms	Cream
Routes of administration	Topical, Topical use

Dosage and administration details:

The topical photosensitizer HAL (Hexvix powder; Photocure ASA, Oslo, Norway), prepared to a 0.2% concentration using a lipid-rich cream base (Unguentum M; Allmiral, Madrid, Spain)

Arm title	MAL arm
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Arm description:

The treatments were given in a randomized, slit-face design, HAL on the other side and MAL on the other side symmetrically.

Arm type	Active comparator
Investigational medicinal product name	MAL
Investigational medicinal product code	
Other name	methyl-aminolaevulinate
Pharmaceutical forms	Cream
Routes of administration	Topical use , Topical

Dosage and administration details:

16% MAL cream (Metvix; Galderma, Paris, France)

Number of subjects in period 1	HAL arm	MAL arm
Started	14	14
Completed	14	14

Baseline characteristics

Reporting groups^[1]

Reporting group title	HAL arm
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Reporting group description:

The treatments were given in a randomized, slit-face design, HAL on the other side and MAL on the other side symmetrically. In total, 14 patientes were recruited and treated in a slit-face design (in total 28 treatment halves)

Reporting group title	MAL arm
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Reporting group description:

The treatments were given in a randomized, slit-face design, HAL on the other side and MAL on the other side symmetrically.

Notes:

[1] - The number of subjects reported to be in the baseline period is not equal to the worldwide number of subjects enrolled in the trial. It is expected that these numbers will be the same.

Justification: The total number of patients was 14, they were treated in a split-face design (each patient was included in both arms)

Reporting group values	HAL arm	MAL arm	Total
Number of subjects	14	14	14
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)	0	0	0
From 65-84 years	10	10	20
85 years and over	4	4	8
65-84	0	0	0
85 and over	0	0	0
Gender categorical			
Units: Subjects			
Female	6	6	6
Male	8	8	8

End points

End points reporting groups

Reporting group title	HAL arm
Reporting group description: The treatments were given in a randomized, slit-face design, HAL on the other side and MAL on the other side symmetrically. In total, 14 patientes were recruited and treated in a slit-face design (in total 28 treatment halves)	
Reporting group title	MAL arm
Reporting group description: The treatments were given in a randomized, slit-face design, HAL on the other side and MAL on the other side symmetrically.	

Primary: Clinical lesion clearance

End point title	Clinical lesion clearance
End point description: The primary outcome measurement was lesion clearance (mean % of baseline lesions per patient who was 100% cleared).	
End point type	Primary
End point timeframe: Three months after the treatment	

End point values	HAL arm	MAL arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	14		
Units: number of actinic keratoses	73	78		

Statistical analyses

Statistical analysis title	Clinical clearance
Statistical analysis description: Wilcoxon signed rank test	
Comparison groups	HAL arm v MAL arm
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.754
Method	Wilcoxon (Mann-Whitney)

Secondary: Histological clearance

End point title	Histological clearance
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End point description:	
Secondary outcome measurements included histological clearance	
End point type	Secondary
End point timeframe:	
Three months after the treatment	

End point values	HAL arm	MAL arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	13		
Units: Histological clearance of actinic kerato	39	70		

Statistical analyses

Statistical analysis title	Histological lesion clearance
Statistical analysis description:	
Wilcoxon signed rank test	
Comparison groups	MAL arm v HAL arm
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.289
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Pain during the treatment and adverse reactions measured separately for both treatment sides.

Assessment type	Systematic
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Dictionary used

Dictionary name	SNOMED CT
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Dictionary version	1
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Reporting groups

Reporting group title	Pain
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Reporting group description:

Patients recorded pain separately on both sides using a visual analogue scale (VAS, 0-10) every 30 minutes during the 2-hour-daylight exposure and every 2 hours until 9 p.m. after therapy.

Reporting group title	Adverse reactions
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Reporting group description:

Local adverse reactions (erythema, oedema, crusting) were assessed 6-7 days after the treatment and classified as follows: minimal I, mild II, intermediate III and severe IV by a blinded investigator. The assesment was done separately for both treatment sides.

The reactions were minimal in 10 HAL and 3 MAL, mild in 3 HAL and 9 MAL, and intermediate in 1 HAL and 2 MAL sites

Serious adverse events	Pain	Adverse reactions	
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	0	0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Pain	Adverse reactions	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 14 (0.00%)	14 / 14 (100.00%)	
Skin and subcutaneous tissue disorders			
Adverse reactions	Additional description: The reactions were minimal in 10 HAL and 3 MAL, mild in 3 HAL and 9 MAL, and intermediate in 1HAL and 2 MAL sites. No severe reactions developed		
subjects affected / exposed	0 / 14 (0.00%)	14 / 14 (100.00%)	
occurrences (all)	0	14	

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study used a "slit-face" design where the patients served as their own controls i.e. the total number of patients enrolled was 14 (two face halves treated, totally 28).
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Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/26011755>