Clinical trial results:
Photodynamic therapy for skin rejuvenation: A pilotstudy evaluating the effectiveness of 5-aminolevulinic acid -based photodynamic therapy in the
treatment of photodamaged skin

Summary

EudraCT number	2015-002537-22
Trial protocol	AT
Global end of trial date	23 January 2018

Results information

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

Trial information

Trial identification

Sponsor protocol code	PDT-PR1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medizinische Universität Wien, Univ. Klinik f. Dermatologie
Sponsor organisation address	Währinger Gürtel 18-20, Vienna, Austria,
Public contact	Univ. Klinik fuer Dermatologie, Medizinische Universitaet Wien, Univ. Klinik fuer Dermatologie, +43 14040077020, sonja.radakovic@meduniwien.ac.at
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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	23 June 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 August 2017
Global end of trial reached?	Yes
Global end of trial date	23 January 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluating the effectiveness of ALA-PDT in patients with photodameged skin concerning cosmetic results and skinageing 6 months after treatment

Protection of trial subjects:

insurance, patient informed consent

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 January 2017
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: 13
Worldwide total number of subjects	13
EEA total number of subjects	13

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)	9
From 65 to 84 years	2
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

13 Patients were recruited between January 2017 and September 2017

Pre-assignment

Screening details:

general medical history, clinical status, informed consent

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	ALA- PDT

Arm description: -

Arm type	ALA-PDT therapy
Investigational medicinal product name	5-aminolaevulinic acid (Ameluz)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Cutaneous use

Dosage and administration details:

BF-200 aminolaevulinic acid was applied to the face 90 minutes before red-light PDT treatment.

Number of subjects in period 1	ALA- PDT
Started	13
Completed	13

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial (overall period)

Reporting group description: -

Reporting group values	Overall trial (overall period)	Total	
Number of subjects	13	13	
Age categorical Units: Subjects			
45-90	13	13	
Age continuous Units: years			
arithmetic mean	62.85		
full range (min-max)	47 to 89	-	
Gender categorical Units: Subjects			
Female	13	13	
Male	0	0	
not specified	0	0	

End points

End points reporting groups

Reporting group title	ALA- PDT

Reporting group description: -

Primary: Changes of the Photoaging Score

End point title	Changes of the Photoaging Score[1]

End point description:

End point type	Primary

End point timeframe:

6 months after first PDT treatment

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: A clinical photoaging score to analyse visual signs of skin ageing was assessed in patients with photodameged skin at baseline and six months after the first treatment. Only descriptive statistics were used.

End point values	ALA- PDT			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: photoageing score	13			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: between patient inclusion and last visit	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	18
Reporting groups	
Reporting group title	ALA-PDT

Reporting group description: -

Serious adverse events	ALA-PDT		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	ALA-PDT		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 13 (100.00%)		
Skin and subcutaneous tissue disorders			
Erythema	Additional description: at the application site		
subjects affected / exposed	13 / 13 (100.00%)		
occurrences (all)	37		
Oedema	Additional description: at/near the application site		
subjects affected / exposed	12 / 13 (92.31%)		
occurrences (all)	30		
Pain			
subjects affected / exposed	13 / 13 (100.00%)		
occurrences (all)	33		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 January 2017	inclusion criteria: age 45-90

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported