Clinical trial results:
THE EFFECT OF AZELAIC ACID ON SYMPTOMS OF ACNE IN FEMALE PATIENTS AGE 20-45 WITH MILD TO MODERATE PAPULOPUSTULAR ACNE (ACNE TARDA)

Summary

EudraCT number	2013-000416-24
Trial protocol	DE
Global end of trial date	04 September 2014

Results information

Result version number	v1 (current)
This version publication date	12 May 2021
First version publication date	12 May 2021
Summary attachment (see zip file)	Acne-A-05 final report (CLINICAL_STUDY_REPORT_CRC_Acne_A_05_final.pdf)

Trial information

Trial identification

Sponsor protocol code	CRC-ACNE-A-05

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Charité-Universitätsmedizin Berlin, Department of Dermatology, Clinical Research Center for Hair and
Sponsor organisation address	Charitéplatz 1, Berlin, Germany, 10117
Public contact	Dr. Kathrin Hillmann, Charité-Universitätsmedizin Berlin, Department of Dermatology, Clinical Research Center for Hair and, 0049 30450518499, kathrin.hillmann@charite.de
Scientific contact	Dr. Kathrin Hillmann, Charité-Universitätsmedizin Berlin, Department of Dermatology, Clinical Research Center for Hair and, 0049 30450518499, kathrin.hillmann@charite.de

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	10 February 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 September 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of this prospective study was to evaluate, whether the treatment with Skinoren® 15% gel leads to a measurable softer and smoother skin besides the improvement of acne symptoms.

Protection of trial subjects:

Azelaic acid is licensed since 2003 for the treatment of acne vulgaris in gel formulation. It leads to a decrease of inflammatory and non-inflammatory acne lesions in patients with acne vulgaris as well as acne tarda, All patients receive a licensed anti acne therapy. Application of the product strictly follows the specifications outlined in the "product characteristics. The product is applied on the facial skin areas affected by acne. In case of severe deterioration or in case of non-response within one month other therapeutic strategies are considered. In case of treatment success Skinoren 15% treatment can be continued.
Azelaic acid is generally well tolerated, whereas at the beginning of local application irritant reactions like pruritus, burning or stinging frequently occur. During therapy appearances of such possible reactions are expected to diminish. These and other possible adverse reactions of azelaic acid like rash, dryness, erythema and pigmentary abnormality will be examined and evaluated and appropriate actions taken during the study. Patients with known allergic reactions to one or more ingredients of the product are excluded.
During the study the patients and their skin are closely monitored. If there is a non-response to treatment or an increase in disease severity, patients are offered alternative therapies. Acna tarda is a chronic condition, thus study participants take advantage of a continuous care. Taking into account the minimal risks and the fact that azelaic acid is a licensed and an effective pharmaceutical for acne patients, the performance of the trial can be considered ethically sound since the expected benefits of the preparations appear greater at present than the risks for the patients. Therefore we consider a positive benefit-to-risk ratio.

Background therapy:

No background therapy

Evidence for comparator:

There was no comparator used

Actual start date of recruitment	09 August 2013
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	Germany: 53
Worldwide total number of subjects	53
EEA total number of subjects	53

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)	53
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Monocenter trial. Screening period was from 9 August 2013 to 20 March 2014.

Pre-assignment

Screening details:

61 patients were screened. 8 were screening failures. 53 were assigned to treatment.

Pre-assignment period milestones

Number of subjects started	61[1]
Number of subjects completed	53

Pre-assignment subject non-completion reasons

Reason: Number of subjects	multiple reasons: 8

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: For reasons of comprehension of the forms, it was not possible for us to enter the number of subjects who had dropped out in the meantime.

Period 1

Period 1 title	Baseline
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Baseline arm

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Azalaic acid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Azelaic acid 15% twice daily

Number of subjects in period 1	Baseline arm
Started	53
Completed	53

Period 2

Period 2 title	Visit 2
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Visit 2 arm

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Azalaic acid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Azelaic acid 15% twice daily

Number of subjects in period 2[2]	Visit 2 arm
Started	47
Completed	47

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: For reasons of comprehension of the forms, it was not possible for us to enter the number of subjects who had dropped out in the meantime.

Period 3

Period 3 title	Visit 3
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Visit 3 arm

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Azalaic acid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:
Azelaic acid 15% twice daily

Number of subjects in period 3[3]	Visit 3 arm
Started	45
Completed	45

Notes:
[3] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: For reasons of comprehension of the forms, it was not possible for us to enter the number of subjects who had dropped out in the meantime.

Period 4

Period 4 title	Visit 4
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Visit 4 arm
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	Azalaic acid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:
Azelaic acid 15% twice daily

Number of subjects in period 4[4]	Visit 4 arm
Started	39
Completed	39

Notes:

[4] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: For reasons of comprehension of the forms, it was not possible for us to enter the number of subjects who had dropped out in the meantime.

Baseline characteristics

Reporting groups	
Reporting group title	Baseline

Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	53	53	
Age categorical			
female patients between 20 and 45 years with mild to moderate acne papulopustulosa were included			
Units: Subjects			
Adults (18-64 years)	53	53	
Gender categorical Units: Subjects			
Female	53	53	
Male	0	0	

End points

End points reporting groups

Reporting group title	Baseline arm
Reporting group description: -	
Reporting group title	Visit 2 arm
Reporting group description: -	
Reporting group title	Visit 3 arm
Reporting group description: -	
Reporting group title	Visit 4 arm
Reporting group description: -	

Primary: Skin Smoothness (SE SM) forehead

End point title	Skin Smoothness (SE SM) forehead[1]
End point description:	
End point type	Primary
End point timeframe:	
Baseline, Visit 2, Visit 3, Visit 4	

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: The requested data regarding the statistical analysis cannot be answered

End point values	Baseline arm	Visit 2 arm	Visit 3 arm	Visit 4 arm
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	47	45	39
Units: eta2				
arithmetic mean (standard deviation)	55.0 (± 20.1)	42.09 (± 11.26)	43.16 (± 11.0)	49.36 (± 16.2)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: During the whole trial	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	no dictionary used
Dictionary version	0

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

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: The adverse events are listed individually in the attached study report.

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