The impact of treatments using cosmetic acids on the skin of people suffering from acne vulgaris

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
08/01/2020		Protocol		
Registration date 17/01/2020	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 14/07/2022	Condition category Skin and Connective Tissue Diseases	[] Individual participant data		

Plain English summary of protocol

Background and study aims

Cosmetic acids are a procedure that can be used for people suffering from acne vulgaris. Both pyruvic acid and azelaic acid can be used for treatments that are aimed at reducing skin greasiness, as well as reducing skin porosity.

The aim of the test is to check how both acids will affect skin parameters, quality of life and if one of these cosmetic acids will be better for acne vulgaris skin.

Who can participate?

Polish female volunteers with mild to moderate acne vulgaris or with healthy skin, aged 18-25

What does the study involve?

Cosmetic acids will be performed on the cleansed face skin, using a cotton stick, then neutralizer will be put on the skin, and rinsed by cold water.

After all the sessions, the follow-up measurements will be made after 14 days.

What are the possible benefits and risks of participating?

Benefits: Improved skin health.

Risks: There is no possible risks of participating, only after treatment skin is a little bit red, but after 1-2 hours it stops.

Where is the study run from?

Opole Medical School - Faculty of Health Science (Poland)

When is the study starting and how long is it expected to run for? January 2020 to April 2020

Who is funding the study?
Opole Medical School (Poland)

Who is the main contact?
Dr Karolina Chilicka
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Study website

http://wsm.opole.pl/3210/5723/projekty-badawcze.html

Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

KB/16/2018

Study information

Scientific Title

The impact of treatments using pyruvic and azelaic acids on selected skin parameters and quality of life from people suffering from acne vulgaris

Study objectives

- 1. Treatment with cosmetic acids decreases the oiling of skin
- 2. Treatment with cosmetic acids increases the quality of life
- 3. Treatment with cosmetic acids acts anti-inflammatory on skin efflorescence

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 13/03/2018, Research Ethics Committee from Opole Medical School (68 Katowicka Street; 45-065; Poland; +48 774410882; biurorektora@wsm.opole.pl), ref: KB/16/2018

Study design

Prospective clinical study with follow-up analysis

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

http://wsm.opole.pl/3210/5723/projekty-badawcze.html

Health condition(s) or problem(s) studied

Acne vulgaris

Interventions

Participants are recruited into 2 groups:

1st group - treatment with pyruvic acid

2nd group - treatment with azelaic acid

Parameters of the skin will be chececked like: oiling, moisturising, poriosity, peeling by device Nati Skin Analyzer.

Six sessions of cosmetic acids are performed every two weeks. After this time skin parameters will be measured (14 days after last session). Skin parameters will be compared between these two groups. Cosmetic acids will be performed on the cleansed face skin, using a cotton stick that, then neutralizer will be used and rinsed by a cold water. After all sessions, the follow-up measurements will be made after 14 days.

Also quality of life will be checked into this two groups, before and after finishing all sessions. DLQI and Skindex-29 will be used.

Intervention Type

Drug

Drug/device/biological/vaccine name(s)

Pyruvic and Azelaic Acids

Primary outcome measure

Skin sebum content measured using the Nati Skin Analyzer at baseline, and two-weeks after finishing the treatments.

Secondary outcome measures

- 1. Skin moisture measured using NAti Skin Analyzer at baseline, two-weeks after finishing the treatments
- 2. Poriosity and peeling of skin will be measured by Nati Skin Analyzer at baseline two-weeks after finishing the treatments
- 3. General quality of life of patients with acne vulgaris measured using the Hellgren and Vincent Scale and also Skindex-29 and DLQI questionnaries at baseline and two weeks after finishing the treatments

Overall study start date

08/01/2018

Completion date

20/04/2020

Eligibility

Key inclusion criteria

- 1. Female aged 18-25 years
- 2. Acne vulgaris

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

25 Years

Sex

Female

Target number of participants

120

Total final enrolment

120

Key exclusion criteria

- 1. Severe acne
- 2. Pregnancy, lactation
- 3. Active inflammation of the skin
- 4. Bacterial, viral, allergic and dungal relapsing skin diseases
- 5. Disturbed skin continuity
- 6. Fresh surgical procedures in the treatment area
- 7. Active Herpes
- 8. Treatment with isotretinoin
- 9. Reduced immunity
- 10. Cancer/tumour
- 11. Skin allegry

Date of first enrolment

27/01/2020

Date of final enrolment

31/01/2020

Locations

Countries of recruitment

Poland

Study participating centre **Opole Medical School**

Katowicka 68 Opole

Poland

45-060

Sponsor information

Organisation

Public Higher Medical Professional School in Opole

Sponsor details

Katowicka 68

Opole

Poland

45-060

+48 (0)774423546

snw@wsm.opole.pl

Sponsor type

University/education

Website

http://wsm.opole.pl/1/strona-glowna.html

ROR

https://ror.org/000bjk220

Funder(s)

Funder type

University/education

Funder Name

Opole Medical School

Results and Publications

Publication and dissemination plan

Publications in peer-reviewed journals.

Intention to publish date

08/06/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/07/2020	31/07/2020	Yes	No
Results article		27/07/2020	14/07/2022	Yes	No