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

Submission date
08/01/2020

Recruitment status
No longer recruiting

Registration date
17/01/2020

Overall study status
Completed

Last Edited
14/07/2022

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
karolina.chilicka@poczta.onet.pl

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

Contact information

Type(s)
Public

Contact name
Dr Karolina Chilicka

ORCID ID
https://orcid.org/0000-0002-6435-0179

Contact details
Opole Medical School
Opole
Poland
45-060
+48 665439443
karolina.chilicka@poczta.onet.pl

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