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Impact of ultrasound to increase medication absorption on skin health and quality of life of acne patients

Submission date	Recruitment status	[X] Prospectively registered
03/01/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/01/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/04/2022	Skin and Connective Tissue Diseases	

Plain English summary of protocol

Background and study aims
Acne is a common skin condition that affects most people at some point. It causes spots, oily skin and sometimes skin that's hot or painful to touch.
Acne medication applied to the skin may have its efficacy improved by the use of high frequency soundwaves (ultrasound) that may increase absorption of the medication by the skin cells. This technique is known as sonophoresis.
This study aims to investigate the effect of sonophoresis on acne treatment.

Who can participate?
Female volunteers aged 19 – 23 years, who suffer with acne vulgaris.

What does the study involve?
Participants will undergo five sessions of sonophoresis performed every seven days using a seboregulating ampoule or placebo gel. Before the treatment series, a week and 14 days after the end of the sessions, skin measurements will be taken and questionnaires will be filled out.

What are the possible benefits and risks of participating?
Benefits: oiling and amount of skin efflorescence will be lower, the moisture of skin will be higher, quality of life will be better after treatments,
No risks

Where is the study run from?
Opole Medical School, Poland

When is the study starting and how long is it expected to run for?
February 2020 to June 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/download/attachment/30539/about-the-project.pdf

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
665439443
karolina.chilicka@poczta.onet.pl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KB/59/NOZ/2019

Study information

Scientific Title
Impact of sonophoresis using a seboregulating ampoule on selected skin parameters and the quality of life acne patients

Study objectives
1. Sonophoresis decreases the oiling of the skin
2. Sonophoresis increases the quality of life
3. Sonophoresis acts anti-inflammatory on skin efflorescence

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/06/2019, Research Ethics Committee from Opole Medical School (68 Katowicka Street; 45-065; Poland; +48 774410882; biurorektora@wsm.opole.pl), ref: KB/59/NOZ/2019

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/download/attachment/30539/about-the-project.pdf

Health condition(s) or problem(s) studied
Acne vulgaris

Interventions
Five sessions of sonophoresis with a seboregulating ampoule (Group A) or placebo (Group B) will be made over seven days. After this time skin parameters will be measured (7 and 14 days after finishing the sonophoresis sessions). Skin sebum (oily secretion) level, hydration and pH of skin will be compared. Five sessions will be performed weekly. After all sessions, the follow-up measurements will be made after 7 and 14 days.

Participants will have skin sebum level, hydration, and pH checked using a Sebumeter, Corneometer, and skin pH meter respectively

Quality of life will be checked by using DLQi and Skindes-29 questionnaires before and after finishing treatments. Parameters of skin will be checked like: oiling of skin, moisturising and pH. Measurements will be made between the eyebrows, 1 cm from the wing of the nose and 1 cm from the lower lip (in the chin area).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Sonophoresis device made by Hebe, Poland (http://www.hebenet.pl/peeling.php)
Seboregulating ampoule (contains: aqua, green tea extract, bambusa vulgaris (bamboo) extract, lactic acid, thymus vulgaris extract, mimose extract, carbomer, caprylyl glycol, sal maris)

Primary outcome measure
Skin sebum content measured using the Sebumeter at baseline, one-week and two-weeks after finishing the treatments

Secondary outcome measures
1. Skin hydration measured using a Corneometer at baseline, one-week and two-weeks after finishing the treatments
2. Transepidermal pH measured using Skin-pH-Meter at baseline, one-week and 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
15/05/2019

Completion date
20/12/2020

Eligibility

Key inclusion criteria
1. Female aged 19-23 years
2. Acne vulgaris

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Severe acne
2. Pregnancy, lactation
3. Active inflammation of the skin
4. Bacterial, viral, allergic and fungal 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. Heart problems (peacemaker)
12. Implants (metal, silicone, saline)
13. Skin allegry
14. Active tuberculosis

Date of first enrolment
04/02/2020

Date of final enrolment
18/02/2020

Locations

Countries of recruitment
Poland

Study participating centre
Opole Medical School
Katowicka 68
Opole
Poland
7542744054

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
15/02/2021

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		05/04/2022	20/04/2022	Yes	No