

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

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

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 seboeregulating 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
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Protocol serial number

KB/59/NOZ/2019

Study information

Scientific Title

Impact of sonophoresis using a seoregulating 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

Primary study design

Interventional

Study design

Prospective clinical study with follow-up analysis

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acne vulgaris

Interventions

Five sessions of sonophoresis with a sebo-regulating 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>)
Sebo-regulating ampoule (contains: aqua, green tea extract, bambusa vulgaris (bamboo) extract, lactic acid, thymus vulgaris extract, mimose extract, carbomer, caprylyl glycol, sal maris)

Primary outcome(s)

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

Key secondary outcome(s)

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 questionnaires at baseline and two weeks after finishing the treatments

Completion date

20/12/2020

Eligibility

Key inclusion criteria

1. Female aged 19-23 years
2. Acne vulgaris

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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 allergy
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

ROR
<https://ror.org/000bjk220>

Funder(s)

Funder type
University/education

Funder Name
Opole Medical School

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes