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

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
03/01/2020		Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
17/01/2020		[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
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# **Contact information**

# Type(s)

Public

#### Contact name

Dr Karolina Chilicka

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# Additional identifiers

# Clinical Trials Information System (CTIS)

Nil known

# ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

## Study type(s)

Treatment

## 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(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 questionnaries 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 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

#### **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			No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes