

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

<b>Submission date</b> 03/01/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/01/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/04/2022	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> 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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**Study website**

<http://wsm.opole.pl/download/attachment/30539/about-the-project.pdf>

## 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/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 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>)  
Seboregulating ampoule (contains: aqua, green tea extract, bambusa vulgaris (bamboo) extract, lactic acid, thymus vulgaris extract, mimosa 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 questionnaires 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 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

**Sponsor details**

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**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?
<a href="#">Results article</a>		05/04/2022	20/04/2022	Yes	No