

# The effect of hydrogen purification on skin condition in women with acne vulgaris

<b>Submission date</b> 26/11/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/12/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/02/2021	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Hydrogen, a natural element with unusual properties, introduced into the skin with the help of a device, primarily slows down the aging process by neutralizing oxygen free radicals, has anti-inflammatory and cleansing effects. The aim of the test is to check how the hydrogen cleansing treatment will affect the skin parameters such as pH, hydration and oiling in healthy and acne vulgaris group.

### Who can participate?

Healthy young Polish female volunteers with mild to moderate acne vulgaris or with healthy skin, aged 19-25

### What does the study involve?

Hydrogen cleansing will be performed on the cleansed face skin, using a special plastic tip that sucks the skin fold and at the same time washing it with hydrogen water (created thanks to the generator in the device). After all sessions, the follow-up measurements will be made after 7 and 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 10 minutes it stops, it is very safe treatment.

### 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 February 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/1/strona-glowna.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  
Katowicka 68  
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/54/NOZ/2019

## Study information

**Scientific Title**

The effect of hydrogen purification on selected skin parameters of healthy women and suffering from acne vulgaris

**Study objectives**

1. Hydrogen purification decreases the oiling of skin
2. Hydrogen purification increases the moisture of skin
3. Hydrogen purification 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/54/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/1/strona-glowna.html>

### **Health condition(s) or problem(s) studied**

Acne vulgaris

### **Interventions**

Participants are recruited into 2 groups:

1st group - healthy women (lower level of sebum)

2nd group - women from mild to moderate acne vulgaris (higher level of sebum)

Other parameters also will be checked: pH and skin hydration. 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).

Four sessions of hydrogen purification are performed weekly. After this time skin parameters will be measured (7 and 14 days after finishing the hydrogen purification sessions). Skin sebum (oily secretion) level, hydration and pH of skin will be compared between these two groups. Hydrogen cleansing will be performed on the cleansed face skin, using a special plastic tip that sucks the skin fold and at the same time washing it with hydrogen water (created thanks to the generator in the device). After all sessions, the follow-up measurements will be made after 7 and 14 days.

### **Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Hydrogen purification

**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 at baseline and two weeks after finishing the treatments

**Overall study start date**

06/05/2019

**Completion date**

25/02/2020

## **Eligibility**

**Key inclusion criteria**

1. Female aged 19 years or above
2. Group A: acne vulgaris
3. Group B: healthy skin

**Participant type(s)**

Mixed

**Age group**

Adult

**Sex**

Female

**Target number of participants**

80 participants

**Total final enrolment**

60

**Key exclusion criteria**

Exclusion criteria for group A (acne vulgaris):

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. Epilepsy
11. Claustrophobia

Exclusion criteria for group B (healthy):

1. Pregnancy, lactation
2. Active inflammation of the skin
3. Bacterial, viral, allergic and fungal relapsing skin diseases
4. Disturbed skin continuity
5. Fresh surgical procedures in the treatment area
6. Active herpes
7. Reduced immunity
8. Epilepsy
9. Claustrophobia

**Date of first enrolment**

07/01/2020

**Date of final enrolment**

07/01/2020

## **Locations**

**Countries of recruitment**

Poland

**Study participating centre**

**Opole Medical School**

Katowicka 68

Opole

Poland

45-060

## **Sponsor information**

**Organisation**

Opole Medical School

### **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.

Protocol and data will be available on the study website.

### **Intention to publish date**

01/08/2020

### **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

01/02/2021

17/02/2021

Yes

No