

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

Submission date 26/11/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/12/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/02/2021	Condition category 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?
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(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 at baseline and two weeks after finishing the treatments

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

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	results	01/02/2021	17/02/2021	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