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

Submission date
26/11/2019

Recruitment status
No longer recruiting

Registration date
09/12/2019

Overall study status
Completed

Last Edited
17/02/2021

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 possibile 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
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Study website
http://wsm.opole.pl/1/strona-glowna.html

Contact information

Type(s)
Public

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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
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Sponsor information

Organisation
Opole Medical School

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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.

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