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Assessment of selected skin parameters and quality of life after cosmetic procedures

Submission date
05/05/2020

Recruitment status
No longer recruiting

Registration date
28/05/2020

Overall study status
Completed

Last Edited
26/05/2023

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
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. The following treatments will be used in the study: carboxytherapy (infusions of carbon dioxide), oxybrasion (exfoliation with oxygen), hydrogen purification (with hydrogen-infused water), and cosmetic acids. Some treatments will be used in a combined manner to check whether it is better to perform one treatment using a device or, for example, combine two types of treatments.

Who can participate?
Female volunteers aged 18 to 25 who suffer with acne vulgaris

What does the study involve?
Six sessions of treatment will be performed with different combinations of carboxytherapy, oxybrasion, cosmetic acids and hydrogen purification. Before the treatment series, 1 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?
Possible benefits include reduced skin oiling and efflorescence (redness), higher skin moisture, and better quality of life after treatments. There are no expected risks.

Where is the study run from?
Public Higher Medical Professional School in Opole (Poland)

When is the study starting and how long is it expected to run for?
October 2020 to June 2024

Who is funding the study?
Public Higher Medical Professional School in Opole (Poland)

Who is the main contact?
Dr Karolina Chilicka
karolina.chilicka@poczta.onet.pl

Study website
http://wsm.opole.pl/3210/5723/projekty-badawcze-pmwsz-w-opolu.html

Contact information

Type(s)
Public

Contact name
Dr Karolina Chilicka

ORCID ID
https://orcid.org/0000-0002-6435-0179

Contact details
Public Higher Medical Professional School in Opole
Katowicka 68
Opole
Poland
45-060
+48 (0)665439443
karolina.chilicka@poczta.onet.pl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KB/57/NOZ/2019

Study information

Scientific Title
Assessment of selected skin parameters and quality of life after cosmetic procedures in people with acne vulgaris and oily skin

Study objectives

1. Cosmetic treatments decrease the oiling of the skin
2. Cosmetic treatments increase the moisture of the skin
3. Cosmetic treatments act anti-inflammatory on skin efflorescence

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/03/2019, Research Ethics Committee from Opole Medical School (68 Katowicka Street; 45-065; Poland; +48 (0)774410882; biurorektora@wsm.opole.pl), ref: KB/57/NOZ/2019

Study design
Prospective randomised parallel clinical study with follow-up analysis

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
http://wsm.opole.pl/3210/5723/projekty-badawcze-pmwsz-w-opolu.html

Health condition(s) or problem(s) studied
Acne vulgaris

Interventions
Current intervention as of 07/09/2020:
Cosmetic treatments will be performed: hydrogen purification, oxybrasion, cosmetic acids, carboxytherapy. The following comparisons of treatments will be made:
1. Oxybrasion (20 people) - hydrogen purification (20 people)
2. Oxybrasion (20 people) - cosmetic acids (20 people)
3. Hydrogen purification (20 people) - cosmetic acids (20 people)
4. Hydrogen purification and cosmetic acids (20 people) - cosmetic acids (20 people)
5. Oxybrasion and cosmetic acids (20 people) - oxybrasion (20 people)
6. Carboxytherapy (20 people) - carboxytherapy and cosmetic acids (20 people)
7. Carboxytherapy (40 people) - carboxytherapy and hydrogen purification (40 people)
8. Carboxytherapy (20 people) - carboxytherapy and oxybrasion (20 people)
9. Microdermabrasion and cosmetic acids (20 people) (added 28/01/2021)

The following parameters will also be checked: oiling, pH and skin hydration, porphyrin measurement, pore size, desquamation. Measurements will be made between the eyebrows, 1 cm from the left and right wing of the nose and 1 cm from the lower lip (in the chin area). Every treatment will be performed over a 14-day interval.

After this time skin parameters will be measured (14 and 30 days after finishing sessions). Skin sebum (oily secretion) level, hydration and pH of skin will be compared between these two groups. Participants will have skin sebum level, hydration, and pH checked using a Sebumeter®, Corneometer®, and skin pH meter respectively. Porphyrin measurement will be taken by Visiopor (Courage Khazaka), desquamation and pore size by Visioscope PC 35 (Courage Khazaka). Quality of life will be checked by using DLQi and Skindes-29 questionnaires before and after finishing treatments. After all sessions, the follow-up measurements will be made after.

The usg of skin will be performed before and after the treatments, to check the collagen fibres (added 21/09/2020).

Also a microbione of the skin will be checked. The sample will be taken by a swab before and after finishing the cosmetic series (added 29/10/2020).

Also questionnaires: COPE, CISS, PH, PKIE, PSS 10, phq9 will be assessed at 14 and 30 days

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Previous intervention:
Cosmetic treatments will be performed: hydrogen purification, oxybrasion, cosmetic acids, carboxytherapy. The following comparisons of treatments will be made:
1. Oxybrasion (20 people) - hydrogen purification (20 people)
2. Oxybrasion (20 people) - cosmetic acids (20 people)
3. Hydrogen purification (20 people) - cosmetic acids (20 people)
4. Hydrogen purification and cosmetic acids (20 people) - cosmetic acids (20 people)
5. Oxybrasion and cosmetic acids (20 people) - oxybrasion (20 people)
6. Carboxytherapy (20 people) - carboxytherapy and cosmetic acids (20 people)
7. Carboxytherapy (40 people) - carboxytherapy and hydrogen purification (40 people)
8. Carboxytherapy (20 people) - carboxytherapy and oxybrasion (20 people)

The following parameters will also be checked: oiling, pH and skin hydration. Measurements will be made between the eyebrows, 1 cm from the left and right wing of the nose and 1 cm from the lower lip (in the chin area). Every treatment will be performed over a 14-day interval.

After this time skin parameters will be measured (14 and 30 days after finishing sessions). Skin sebum (oily secretion) level, hydration and pH of skin will be compared between these two groups. 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. After all sessions, the follow-up measurements will be made after.

Also questionnaires: COPE, CISS, PH, PKIE, PSS 10, phq9 will be assessed at 14 and 30 days (added 27/07/2020)

Intervention Type
Procedure/Surgery

Primary outcome measure
Skin sebum content measured using the Sebumeter at baseline, 1 week and 2 weeks after finishing the treatments

Secondary outcome measures

1. Skin hydration measured using a Corneometer at baseline, 1 week and 2 weeks after finishing the treatments
2. Transepidermal pH measured using Skin-pH-Meter at baseline, day 14 and 30 after finishing the treatments
3. General quality of life measured using the Hellgren and Vincent scale and also Skindex-29 and DLQI questionnaries at baseline and 2 weeks after finishing the treatments

Overall study start date
10/02/2020

Completion date
21/06/2024

Eligibility

Key inclusion criteria
1. Female aged 18-25
2. Acne vulgaris

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
25 Years

Sex
Female

Target number of participants
320

Total final enrolment
44

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. Epilepsy
11. Claustrophobia

Date of first enrolment
01/10/2020

Date of final enrolment
30/10/2020

Locations

Countries of recruitment
Poland

Study participating centre
Public Higher Medical Professional School in Opole
Katowicka 68
Opole
Poland
45-060

Sponsor information

Organisation
Public Higher Medical Professional School in Opole

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
Public Higher Medical Professional School in Opole

Results and Publications

Publication and dissemination plan
Publications in peer-reviewed journals.

Intention to publish date
09/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Karolina Chilicka (karolina.chilicka@poczta.onet.pl).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Oxybrasion	01/07/2022	14/07/2022	Yes	No
Results article		19/05/2023	26/05/2023	Yes	No