ISRCTN41899475 https://doi.org/10.1186/ISRCTN41899475

Trichloroacetic acid chemical peel in anti-aging skin therapy in perimenopausal and postmenopausal women

Submission date
20/08/2021

Recruitment status
No longer recruiting

Registration date
28/09/2021

Overall study status
Completed

Last Edited
24/03/2025

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
Trichloroacetic acid (TCA) peels are well-known skin treatments used to treat skin discolouration, scarring and wrinkles, but to this day mostly traditional TCA peel compositions have been used. Those peels result in damage to the epidermis (the upper layer of the skin) and the upper layer of the dermis. The modern TCA formula stimulates internal renewal and regenerates the deepest layers of the skin in a very gentle way without damaging the skin surface. There are few studies using novel TCA peel and the research results are promising. The researchers emphasize the need for further research, in particular of women of different ages. The aim of this study is to assess the effectiveness of a novel TCA chemical peel in the anti-aging treatment of facial skin in perimenopausal and postmenopausal women.

Who can participate?
40-58-year-old perimenopausal women and 59-65-year-old postmenopausal women

What does the study involve?
The patients will be divided into four groups – two experimental groups and two control groups. Women in the experimental groups will receive TCA chemical peel treatment. Women in the control groups will receive sham TCA chemical peel treatment

What are the possible benefits and risks of participating?
The results of the study will broaden the knowledge on the anti-aging effectiveness of TCA chemical peel in perimenopausal and postmenopausal women. The results of the study will contribute to the development of effective anti-aging facial skin treatments. Possible risks of TCA chemical peel are redness, slight swelling and a feeling of warmth of the skin.

Where is the study run from?
Academy of Physical Education in Katowice (Poland)

When is the study starting and how long is it expected to run for?
November 2020 to December 2022

Who is funding the study?
Academy of Physical Education in Katowice (Poland)

Who is the main contact?
Laura Piejko
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Ref No. 3/2020

Study information

Scientific Title
Assessment of the effects of trichloroacetic acid chemical peel in anti-aging skin therapy in perimenopausal and postmenopausal women

Study objectives
Trichloroacetic acid (TCA) chemical peel will affect skin therapy in perimenopausal and postmenopausal women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/12/2020, the Research Bioethics Committee of the Academy of Physical Education in Katowice (Mikołowska 72a Street, 40-065 Katowice, Poland; +48 (0)322075152; komisjabioetyczna@awf.katowice.pl), ref: 3/2020

Study design
Single-centre interventional double-blinded randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Anti-aging skin therapy in perimenopausal and postmenopausal women

Interventions
The intervention will consist of two stages. The trial participants will be 46 perimenopausal and 46 postmenopausal women. Participants will be qualified for the trial by a cosmetic dermatologist and will be informed about the procedure and will be asked for written consent. After agreeing to participate in the study, trial participants will be randomly divided into two groups in the first and the second stage of the experiment. Randomisation will be based on codes placed in sealed and opaque envelopes. Women randomly included in the groups will not be aware of which group they are in during the study, but after the end of the trial, they will be informed by the study director of which group they were in.

Description of the procedure in the experimental group (TCA peel) - the same in the two experimental groups:
1. Make-up removal and cleansing of the skin.
2. Protecting sensitive areas (eye corner, eyebrows, lips) with petroleum jelly.
3. Chemical peel: three layers of trichloroacetic acid (TCA) at a concentration of 34% will be applied on the skin and rubbed. After each layer, the skin will be hydrated with water. In sensitive skins, the preparation will be rubbed more gently. After the last layer the peeling will be washed off with water and a cream with sunscreen SPF 50+ will be applied.
4. A series of four treatments every 7 days will be conducted.

Composition of TCA chemical peel PQ Age Evolution® (PromoItalia, Italy):
1. Trichloroacetic acid 34% (TCA), which removes discolouration and small scars, smoothes the skin, reduces blackheads and affects the synthesis of collagen.
2. Kojic acid 10% with antibacterial and antifungal properties and combats discoloration. The action of the acid is based on inhibiting the biosynthesis of melanin, the main pigment in the skin. It removes dark spots on the skin and stimulates skin renewal.
3. 5% urea peroxide with lightening properties.
4. Coenzyme Q10 5% with antioxidant properties.

Description of the procedure in the control group (sham TCA): the same in the two control groups
1. Make-up removal and cleansing of the skin.
2. Protecting sensitive areas (eye corner, eyebrows, lips) with petroleum jelly.
3. Sham peel: three layers of ultrasound gel will be applied and rubbed into the skin. After each layer, the skin will be washed off with water. In the case of sensitive skin, the ultrasound gel will be rubbed more gently. After the last layer, the face with be washed with water and a cream with sunscreen SPF 50+ will be applied.
4. A series of four treatments every 7 days will be conducted.

All procedures will be carried out by an experienced therapist.

To blind the examination, the personnel performing the procedure (two experienced therapists) will not know what substance will be used. The person preparing the treatment vials will be the senior researcher who will fill new vials with a TCA peel or inactive substance (ultrasound gel) and will place the vials on the treatment site before therapists will perform the treatments. An additional advantage that enables blindness is the fact that the peeling procedure is painless and the post-peel exfoliation is practically imperceptible.

The patients will be arranged at different times so that they are not able to contact each other during the procedure.

The effectiveness of therapy will be assessed by medical devices and questionnaires listed below.

Intervention Type
Other

Primary outcome measure
1. Skin hydration measured by Corneometer® MC750 B2 (Courage + Khazaka Electronic GmbH, Cologne, Germany) at baseline, 1 month and 3 months after treatment.
2. Skin elasticity measured by Cutometer® MC750 B2 (Courage + Khazaka Electronic GmbH, Cologne, Germany) at baseline, 1 month and 3 months after treatment
3. Wrinkle appearance measured by series of photos with the Canon EOS60D camera at baseline, 1 month and 3 months after treatment.
5. Wrinkle appearance measured by series of photos with the Fujifilm XT1 camera at baseline, 1 month and 3 months after treatment.
6. Wrinkle appearance measured by series of photos with the DUB SkinScanner 75 at baseline, 1 month and 3 months after treatment.
7. Wrinkle appearance measured by series of photos with the Artec Leo Easy 3D scanner at baseline, 1 month and 3 months after treatment.
8. Wrinkle appearance measured by series of photos with the Firely DE300 Digital Video Dermatoscope at baseline, 1 month and 3 months after treatment.

9. Wrinkle appearance measured by series of photos with the Wrinkle Severity Rating Scale at baseline, 1 month and 3 months after treatment.
10. Skin discoloration and redness measured by Mexameter® MC750 B2 (Courage + Khazaka Electronic GmbH, Cologne, Germany) at baseline, 1 month and 3 months after treatment.

Secondary outcome measures
1. Skin sebum secretion measured by Sebumeter® MC750 B2 (Courage + Khazaka Electronic GmbH, Cologne, Germany) at baseline, 1 month and 3
months after treatment.
2. Skin aesthetic improvement measured by the Patient's Aesthetic Improvement Scale (PAIS) at baseline, 1 month and 3 months after
treatment.
3. Skin aesthetic improvement measured by the Global Aesthetic Improvement Scale (GAIS) at baseline, 1 month and 3 months after
treatment.
4. Skin aesthetic improvement measured by the Artec Leo Easy 3D scanner at baseline, 1 month and 3 months after treatment.
5. Skin aesthetic improvement measured by the DUB SkinScanner 75 at baseline, 1 month and 3 months after treatment.

Overall study start date
17/11/2020

Completion date
21/12/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 03/01/2023:

1st stage of intervention participant inclusion criteria:
1. Age of 40-58 years and menstruation for the group of perimenopausal women
2. Patient consent for the trial
3. Fitzpatrick skin type 2-3
4. Contraindications for chemical exfoliation (bacterial, viral or fungal infections, other inflammatory dermatoses such as psoriasis and topical dermatitis, topical retinoids treatment, keloid and scarring tendency)
5. No previous treatments of TCA chemical peels
6. No previous exfoliating and rejuvenating treatments within the previous 6 months, including chemical peels, microneedle radiofrequency, fractional ablation laser, microneedling therapy etc

2nd stage of intervention participant inclusion criteria:
1. Age 59-65 years for postmenopausal women
2. Patient consent for the trial
3. Fitzpatrick skin type 2-3
4. Contraindications for chemical exfoliation (bacterial, viral or fungal infections, other inflammatory dermatoses such as psoriasis and topical dermatitis, topical retinoids treatment, keloid and scarring tendency)

5. No previous treatments of TCA chemical peels
6. No previous exfoliating and rejuvenating treatments within the previous 6 months, including chemical peels, microneedle radiofrequency, fractional ablation laser, microneedling therapy etc

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Previous inclusion criteria:

1st stage of intervention participant inclusion criteria:
1. Age of 40-58 years and menstruation for the group of perimenopausal women
2. Patient consent for the trial
3. Fitzpatrick skin type 2-3
4. Contraindications for chemical exfoliation (bacterial, viral or fungal infections, other inflammatory dermatoses such as psoriasis and topical dermatitis, topical retinoids treatment, keloid and scarring tendency)
5. No previous treatments of TCA chemical peels
6. No previous exfoliating and rejuvenating treatments within the previous 6 weeks, including chemical peels, microneedle radiofrequency, fractional ablation laser, microneedling therapy etc

2nd stage of intervention participant inclusion criteria:
1. Age 59-65 years for postmenopausal women
2. Patient consent for the trial
3. Fitzpatrick skin type 2-3
4. Contraindications for chemical exfoliation (bacterial, viral or fungal infections, other inflammatory dermatoses such as psoriasis and topical dermatitis, topical retinoids treatment, keloid and scarring tendency)
5. No previous treatments of TCA chemical peels
6. No previous exfoliating and rejuvenating treatments within the previous 6 weeks, including chemical peels, microneedle radiofrequency, fractional ablation laser, microneedling therapy etc

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
92

Key exclusion criteria
Participant exclusion criteria (the same for the two experimental and control groups):
1. Contraindications to chemical exfoliation (local infections etc)
2. Malignancy
3. Pregnancy and breastfeeding
4. No possibility to participate in follow-up visits
5. History of mental illness and unrealistic expectations about the results of the study

Date of first enrolment

30/09/2021

Date of final enrolment
01/08/2022

Locations

Countries of recruitment
Poland

Study participating centre
The Jerzy Kukuczka Academy of Physical Education in Katowice
Institute of Physiotherapy and Health Sciences
72a Mikołowska Street
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Sponsor type
University/education

Website
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Funder(s)

Funder type
University/education

Funder Name
Akademia Wychowania Fizycznego im. Jerzego Kukuczki w Katowicach

Alternative Name(s)
The Jerzy Kukuczka Academy of Physical Education in Katowice, AWF Katowice

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Results and Publications

Publication and dissemination plan
PhD dissertation and publication in a scientific journal. The study protocol and the statistical analysis plan etc will not be published. After the studies are finished the clinical trial database is planned to be published. At present no additional documents (such as study protocol, statistical analysis plan, etc) are available to be uploaded.

Intention to publish date
01/05/2023

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/10/2023	03/12/2024	Yes	No
Results article		01/02/2025	24/03/2025	Yes	No