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Procedures of effectiveness of aesthetic and cosmetic methods

Submission date	Recruitment status
16/12/2024	No longer recruiting
Registration date	**Overall study status**
18/12/2024	Completed
Last Edited	**Condition category**
18/12/2024	Skin and Connective Tissue Diseases

- [ ] Prospectively registered
- [ ] Protocol
- [ ] Statistical analysis plan
- [ ] Results
- [ ] Individual participant data
- [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to evaluate the effects of certain cosmetic creams on the skin of healthy volunteers. Researchers will use biophysical methods and skin biopsies to assess the impact of these creams, both alone and in combination with laser treatments.

Who can participate?
Healthy male and female volunteers aged 18 to 65 years can participate in this study.

What does the study involve?
Participants will apply either an active cream or a placebo cream to the inner surface of both arms twice daily (morning and evening) for two weeks. The study will measure transdermal water loss, erythema, pigmentation, and keratin hydration using the MPA 5 device at Day 1 and Day 14. Elasticity will be measured using the Cutometer 575 device at the same time points. Additionally, small skin biopsies will be taken before starting the cream application and after 14 days to assess collagen improvement.

What are the possible benefits and risks of participating?
The study aims to demonstrate the effectiveness of the active ingredients in the cosmetic formulations. The results will help understand how these ingredients and treatments affect the skin. While the non-invasive tests are safe, the skin biopsies are minimally invasive and carry a small risk of discomfort or minor complications.

Where is the study run from?
Established Laboratory of Chemistry - Biochemistry - Cosmetology, Department of Biomedical Sciences, University of West Athens, Aegaleo Alsace Campus (Greece)

When is study starting and how long is it expected to run for?
November 2021 to July 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

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Public, Principal investigator

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
CPMS37942

Study information

Scientific Title
Procedures of effectiveness of aesthetic and cosmetic methods

Acronym
PEACM

Study objectives
Study with biophysical methods and skin biopsies to evaluate the effect on the skin of healthy volunteers of
a) cosmetic creams of Unisooth EG-28® mixture before and after Nd:YAG or Diode laser or microcrystal dermabrasion or dermaroller and
b) the Unisooth EG-28® ingredient with iontophoresis device and external application of cosmetic cream with active ingredient Olea vitae PLF®.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/11/2021, UNIWA RESEARCH ETHICS COMMITTEE (Agiou Spyridonos 28, Aigaleo, 12243, Greece; +30 2105387294; ethics@uniwa.gr), ref: 37942/05-11-2021

Study design
Randomized double blind placebo controlled study

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Skin condition in healthy volunteers

Interventions
Group 1: Used OLEA VITAE™ 02 cream.
Group 2: Used placebo cream.

Intervention: Each participant received a coded vessel containing 70 g of either the active cream or placebo cream, without indication of its contents.
Application: Participants applied the cream to the inner surface of both arms twice daily (morning and evening) for two weeks.
Instructions: Participants were instructed not to apply their test cream in the twelve hours prior to the baseline visit.

Total Duration of Intervention: 2 weeks.
Follow-Up: Skin biopsies were performed at baseline (Day 0) and after 14 days of treatment (Day 14).

Intervention Type
Supplement

Primary outcome(s)
1. Transdermal water loss is measured using Tewameter MPA-5 at Day 0 and Day 14
2. Erythema is measured using Mexameter MPA-5 at Day 0 and Day 14
3. Pigmentation is measured using Mexameter MPA-5 at Day 0 and Day 14
4. Keratin hydration is measured using Corneometer CM 825 at Day 0 and Day 14
5. Elasticity is measured using Cutometer MPA 580 at Day 0 and Day 14
6. Collagen improvement is measured using skin biopsy at Day 0 and Day 14

Key secondary outcome(s))
Satisfaction and product tolerability measured using a questionnaire at the end of the treatment

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Volunteer individuals aged 18 to 65 years, either sex
2. Written and informed consent
3. Healthy volunteers without skin disease or any other diseases (acute or chronic)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
45

Key exclusion criteria
1. Pregnancy, lactating, or planned pregnancy
2. People who use external application containing steroids for the treatment of skin disease more than one month
3. Participated in the same trial within six months from the interview
4. People with hypersensitive skin
5. Skin abnormalities such as severe acne, erythema, telangiectasia on the test site
6. Used the same or similar cosmetic (or pharmaceutical) on the test site within three months

from the interview
7. Have peeling of skin or wrinkles removed within six months from the interview
8. Other unsuitable reasons for clinical trial based on the discretion of the investigator

Date of first enrolment
01/09/2022

Date of final enrolment
30/12/2022

Locations

Countries of recruitment
Greece

Study participating centre
ESTABLISHED LABORATORY OF CHEMISTRY - BIOCHEMISTRY - COSMETOLOGY, DEPARTMENT OF BIOMEDICAL SCIENCES, UNIVERSITY OF WEST ATHENS, AEGALEO ALSACE CAMPUS
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Sponsor information

Organisation
UNIWA

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study are not expected to be made available due to university policy

IPD sharing plan summary

Not expected to be made available