

The skin improvement effect of two skin cream products

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| Submission date 30/03/2023 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 11/05/2023 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 05/12/2023 | Condition category Skin and Connective Tissue Diseases | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Skin changes are one of the representative symptoms of ageing. The aim of this study is to investigate the effects of plant extracts on the skin, focusing specifically on whether they help reduce skin wrinkles and moisturise the skin.

Who can participate?

Healthy women aged 30-59 years

What does the study involve?

The cream was made in two types, one was the A cream and the other was a placebo (dummy cream) for estimating the effects of plant extract. All participants put on this cream two times per day for 4 weeks, the A cream on the left side of the face and the placebo on the right. A questionnaire is completed before using the cream, after 2 weeks, and after 4 weeks. Skin wrinkles and skin moisturizing levels are assessed.

What are the possible benefits and risks of participating?

The participants may benefit from reduced skin wrinkles and moisturised skin. However, only one side of the face may improve.

Where is the study run from?

Global Medical Research Center (South Korea)

When is the study starting and how long is it expected to run for?

October 2021 to November 2021

Who is funding the study?

Ministry of Food and Drug Safety (South Korea)

Who is the main contact?

Prof. Jae youl Cho, jaecho67@gmail.com

Contact information

Type(s)

Scientific

Contact name

Prof Jae youl Cho

ORCID ID

<https://orcid.org/0000-0001-8141-9927>

Contact details

2066 Seobu-ro

Jangan-gu

Suwon-si

Gyeonggi-do

Suwon

Korea, South

16419

+82-031-290-7878

jaecho67@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

NCT05872113

Protocol serial number

GIRB-21929-NY

Study information

Scientific Title

Product A (test product), product B (control product) evaluation of human efficacy for skin moisturization and wrinkle improvement

Acronym

TSIEOCFA2P

Study objectives

Product A reduces skin wrinkles and upregulates skin moisture levels more than product B

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 01/10/2021, Institutional Review Board of Global Medical Research Center (82, Naruteo-ro, Seocho-gu, Seoul, Republic of Korea; +82 (0)70 4139 0795; girb@gmrc.co.kr), ref: GMRC-21O08-EA1

Study design

Interventional double-blind randomized placebo-controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Dry skin

Interventions

The cream was made in two types, one was the A cream and the other was a placebo (dummy cream) for estimating the effects of plant extract. All participants put on this cream two times per day for 4 weeks, the A cream on the left side of the face and the placebo on the right. A questionnaire is completed before using the cream, after 2 weeks, and after 4 weeks. Skin wrinkles and skin moisturizing levels are assessed.

Intervention Type

Supplement

Primary outcome(s)

The skin wrinkle is measured using a visual assessment using an Antera 3D CS (Miravex, Ireland) at baseline, 0, 2, and 4 weeks. The skin moisture level was conducted using a Corneometer CM825 (Courage and Khazaka, Köln, Germany) at baseline, 0, 2, and 4 weeks.

Key secondary outcome(s)

The skin wrinkle is measured using a visual assessment using an Antera 3D CS (Miravex, Ireland) at baseline, 0, 2, and 4 weeks. The skin moisture level was conducted using a Corneometer CM825 (Courage and Khazaka, Köln, Germany) at baseline, 0, 2, and 4 weeks.

Completion date

16/11/2021

Eligibility

Key inclusion criteria

1. Females with dried skin, aged 30-59 years
2. The subject has eye wrinkles (crow's feet)
3. A person who has voluntarily signed consent after fully explaining the test purpose and content
4. Those who can follow up during the test period
5. A healthy person without acute or chronic physical disease including skin disease

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

21

Key exclusion criteria

1. Pregnant or lactating women and women of childbearing age who do not agree to the contraceptive method prescribed by the protocol
2. A person with a lesion at the test site or suffering from an infectious skin disease
3. People with allergies or hypersensitivity, or irritation to cosmetics, pharmaceuticals, or daily exposure to light
4. Those who have received systemic steroids or phototherapy within 1 month of participating in the trial, or who have received skin treatment (scaling/botox/filler/laser/tattoo) within 3 months of participating in the trial
5. Those who have used drugs with similar functions at the research site within 3 months before the start of the study, or have a mental illness, or mental retardation disorder
6. Other than the above, a person who will make it difficult to conduct a human test based on the judgment of the responsible researcher or the person in charge of the study

Date of first enrolment

01/10/2021

Date of final enrolment

07/10/2021

Locations**Countries of recruitment**

Korea, South

Study participating centre

Global Medical Research Center

107, Dosan-daero

Gangnam-gu

Seoul

Korea, South

06035

Sponsor information

Organisation

COSMAX

Funder(s)

Funder type

Government

Funder Name

Ministry of Food and Drug Safety

Alternative Name(s)

MFDS

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Korea, South

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| Results article | | 24/05/2023 | 05/12/2023 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |