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The skin improvement effect of two skin cream products

Submission date
30/03/2023

Recruitment status
No longer recruiting

Registration date
11/05/2023

Overall study status
Completed

Last Edited
05/12/2023

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT05872113

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

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
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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/10/2021

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

Age group
Adult

Sex
Female

Target number of participants
22

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
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Sponsor information

Organisation
COSMAX

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Sponsor type
Industry

Website
https://www.cosmax.com/main.asp

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

Publication and dissemination plan
Planned publication in MDPI journal

Intention to publish date
31/03/2023

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