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Food supplement effect on ageing signs

Submission date
03/11/2025

Recruitment status
No longer recruiting

Registration date
13/11/2025

Overall study status
Completed

Last Edited
12/11/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
This study is conducted to assess and compare whether two oral collagen food supplements can improve the appearance of skin aging signs, nails, body and hair. The principal criterion of the study is the firmness of the skin after 1 and 3 months of use. The results will be compared to a placebo.

Who can participate?
Healthy women between 45 and 65 years of age, with early signs of menopause or post-menopausal and with skin aging, specifically firmness and wrinkles.

What does the study involve?
This is a double blind, randomized and monocentric study. The Subjects will take one of the food supplements or the corresponding placebo once daily for 3 months. Skin measurements (firmness, wrinkles, elasticity, hydration), hair (thickness), and nails (strength and thickness) will be taken at the beginning of the study, after 1 month, and after 3 months. Clinical evaluations by experts and instrumental assessments will be carried out. Participants will also fill in questionnaires and keep a daily log.

What are the possible benefits and risks of participating?
Possible Benefits: improvement of their skin aging, hair, and nails.
Possible Risks: side effects that can occur during the study will be monitored and recorded in a daily log.

Where is the study run from?
The sponsor of the study is Vichy Laboratoires, and SGS Proderm is the CRO center which runs the study in Germany.

When is the study starting and how long is it expected to run for?
Participation will take place between February 2025 to May 2025. The total treatment duration for each participant is 3 months.

Who is funding the study?
The study is funded by L'Oréal / CAI VICHY (France).

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Sponsor Code VCY24-009, proDERM Code 25.0008-23

Study information

Scientific Title
Comparaison of 2 Nutricosmetics containing collagen on skin, body, hair and nail aging signs in women for 3 months

Study objectives
The aim of this study is to investigate the cosmetic effect of two oral collagen food supplements on different skin ageing signs after 1 and 3 months of intake compared to their respective placebo groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/01/2025, Institutional Review Board (Kiebitzweg 2, Schenefeld, D-22869, Germany; +49 (0)40 839358-0; IRB@proderm.de), ref: 2025/003

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Single

Purpose
Prevention

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied

Healthy female subjects between 45 and 65 years of age, Fitzpatrick skin type I – III, with aging signs

Interventions

Subjects take 3 food supplement tablets once daily for 3 months at home in the morning, drinking 1 cup of water during intake if necessary. In case intake was forgotten, the subjects shall not take the forgotten dose at another time. Then efficacy and safety assessments are carried out.

• Active nutricosmetic A
• Placebo nutricosmetic B
• Active nutricosmetic C
• Placebo nutricosmetic D

Randomization process:
The validated randomization function of secuTrial® will be used to assign the treatments A to D (1:1:1:1:1 ratio) employing an allocation procedure according to Pocock & Simon (Variance Minimization) to achieve the best possible balance regarding different strata e.g. STRATA 1 "age", STRATA 2 "BMI", STRATA 3 "menopausal status", STRATA 4 "firmness score on cheeks" and STRATA 5 "protein intake".
The STRATA level for "age" will be 3 types: 45 – 50 years, 51 – 60 years and 61 – 65 years.
The STRATA level for "BMI" will be 2 types: 20 – 25 kg/m2 and 26 – 30 kg/m2.
The STRATA level for "menopausal status" will be 3 types: pre-menopausal, post-menopausal for 1 – 5 years and post-menopausal for 6 – 10 years.
The STRATA "firmness score on cheeks" (assessment on day 0) will be 2 types: 3 – 4 and 5 – 6.
The STRATA "protein intake" (sourced from meat, fish, egg, legumes, nuts, dairy products) will be 3 types: never to 3 times per week, 4 times per week to once a day and many times a day.
60 subjects will use one treatment: code A, B, C or D. A manual assignment of the last subjects to one of the treatment groups may be necessary to obtain equal numbers of subjects in each treatment group.

Intervention Type

Supplement

Primary outcome(s)

The skin firmness is measured using a Visual Analogue Scale (VAS) at baseline and after 1 and 3 months

Key secondary outcome(s))

The following secondary outcome measures were assessed at baseline and after 1 and 3 months:
1. Skin smoothness, elasticity and tonicity measured using a Visual Analogue Scale (VAS)
2. Wrinkles measured using the Atlas scale and AEVA
3. Hair thickness measured using TrichoLAB
4. Nail strength measured using Nail StrainStress Meter
5. Skin elasticity, firmness and viscoelasticity measured using a cutometer
6. Skin hydration measured using a corneometer
7. Skin density measured using ultrasound
8. Standardized pictures taken with Visia CR
10. Efficacy and tolerance were measured using a questionnaire after 1 and 3 months

Completion date

30/05/2025

Eligibility

Key inclusion criteria
1. Written informed consent to participate in the study and to allow photo usage for illustrative and/or research purposes
2. Willingness to actively participate in the study and to come to the scheduled visits
3. Healthy subjects (according to investigator or designee)
4. Female
5. Caucasian
6. From 45 to 65 years of age
7. Menopausal* (from 1 year to 10 years) *Menopausal = women having at least 1 year without menstruation
8. Pre-menopausal with first symptoms of the menopause (e.g. hot flashes, irregular menstruation, intensity of menstruation flow, mood changes, myalgia, headaches, insomnia, etc)
9. BMI (body mass index) ≥ 20 and ≤ 30 kg/m2
10. Skin firmness ≥ 3 and ≤ 6 on the cheeks (on a 10 points scale)
11. Phototype I, II or III
12. Nail length of at least 4 mm
13. Hair length of at least 2 cm
14. Pre-menopausal females: using adequate contraception (implants, injectables, combined oral contraceptives, some intrauterine-devices, sexual abstinence or vasectomised partner, cosexual partner, condom)
15. Preferably subjects with no cigarette consumption or 1-2 cigarettes a week, if necessary smoker but with no increase of the cigarette consumption will be accepted to complete the panel
16. Preferably, subjects with no alcohol consumption or 1-2 glasses a week , if necessary subjects with no increase of the alcohol consumption will be accepted to complete the panel
17. Menopausal females: Preferably, subjects with no hormonal replacement therapy, if necessary subjects with no beginning or modification of hormonal replacement therapy will be accepted to complete the panel

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
45 years

Upper age limit
65 years

Sex
Female

Total final enrolment
232

Key exclusion criteria
Nutrition
1. Documented allergies to food supplements and/or ingredients, to eggs
2. Intake of own food supplements (including vitamins and minerals) or other active compounds which may have an effect on skin 2 months prior to the start of the study and throughout the entire course of the study (excluding food supplements provided during the study)
3. Modification of weight of more than 5 kg 2 months prior to the start of the study

Habits and practices
1. Drug addicts, alcoholics
2. Application of self-tanning products on the test area 4 weeks prior to the start of the study and/or throughout the entire course of the study
3. Nail biting habit
4. Employee of the study site
5. Aesthetic procedures (such as chemical peeling, lasers, dermabrasions, injections, anti-ageing mask, hair implant etc ….) performed in beauty salon or in medical offices at the test areas to be measured / assessed that could influence the investigation for 6 months prior to the start of the study
6. Application of peeling products at home on the test area 4 weeks prior to the start of the study and/or throughout the entire course of the study
7. Application of depigmenting cosmetic products and / or retinol based-cosmetics (or derivative), vitamin C based-cosmetic (or derivative) or AHA based-cosmetic on the evaluation areas 4 weeks prior to the start of the study and/or throughout the entire course of the study
8. Excessive sun exposure (natural or artificial - thus/visibly tanned) on the concerned areas 4 weeks prior to the start of the study and/or throughout the entire course of the study
9. Anti-aging cosmetic products and/or cosmetic products claiming efficacy on the skin firmness and wrinkles on the evaluation areas 2 weeks prior to the start of the study and/or throughout the entire course of the study
10. Visit the sauna or hammam 2 weeks prior to the start of the study

Hormonal status
Pre-menopausal females: Planned start or modification of oestro-progestogen treatment during the course of the study

Global condition and health
1. Pre-menopausal females: Pregnancy or lactation
2. AIDS, HIV-positive or infectious hepatitis
3. Conditions which exclude a participation or might influence the test reaction/evaluation
4. Participation or being in the waiting period after participation in cosmetic and/or pharmaceutical studies pertaining to the test area
5. Cancer not being diagnosed as cured and requiring chemotherapy, irradiation and/or hormonal treatment within the last 2 years
6. One of the following illnesses with reduced physical capability/fitness: asthma (symptom-free allergic asthma is not an exclusion criterion), hypertension, cardiovascular diseases
7. Insulin-dependent diabetes mellitus
8. Active skin disease on the head, hands, thigh and volar forearms like acute dermatitis, that requires actual topical medication on the test area and/or systemic drug treatment according to a physician

9. Wounds, moles, tattoos, scars, irritated skin, excessive hair growth, etc. at the test areas to be measured / assessed that could influence the investigation
10. Epilepsy
11. Chronic gastrointestinal diseases
12. Application of a treatment (oral or topical) with tretinoin or isotretinoin or corticosteroid 8 weeks prior to the start of the study and/or throughout the entire course of the study
13. Systemic therapy with immuno-suppressive drugs (e.g. corticosteroids) throughout the entire course of the study
14. Systemic long-term therapy with anti-phlogistic agents or analgetics (e.g. diclophenac), except for minor pain relief medicine like acetylsalicylic acid or paracetamol within the last 3 days prior to the start of the study
15. Instructions for subjects

Date of first enrolment
03/02/2025

Date of final enrolment
21/02/2025

Locations

Countries of recruitment
Germany

Study participating centre
SGS proderm GmbH
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Sponsor information

Organisation
L'Oréal / CAI VICHY

Funder(s)

Funder type
Industry

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication