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# Clinical study for the evaluation of the anti-ageing properties of a food supplement

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| **Submission date**<br>07/07/2026 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol |
| **Registration date**<br>07/07/2026 | **Overall study status**<br>Ongoing | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>07/07/2026 | **Condition category**<br>Other | [_] Individual participant data<br>[X] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

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# Additional identifiers

### Study code
IT0008187b/25

# Study information

### Scientific Title
Clinical study for the evaluation of the antiageing properties of a food supplement. Controlled study vs placebo

### Study objectives
The study aims to assess the efficacy of a food supplement, in improving skin conditions. In particular, the supplement’s anti-aging efficacy and its overall benefits on skin health will be investigated by evaluating skin elasticity, firmness, profilometry (wrinkle depth), skin moisturization, skin radiance and skin fiber structure (dermis and epidermis). Objective and subjective assessments of product efficacy will be also assessed through self-assessment questionnaires.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 08/04/2026, International Ethics and Integrity Committee (IEIC) (Via Per Garbagnate 61, Lainate, 20045, Italy; +39 3783037302; secretariat@ieicomittee.com), ref: IC009A

### Primary study design
Interventional

### Allocation
Randomized controlled trial

### Masking
Blinded (masking used)

### Control
Placebo

### Assignment
Parallel

### Purpose
Efficacy

### Study type(s)

### Health condition(s) or problem(s) studied
Healthy subjects with phototype II-IV (according to Fitzpatrick scale), presenting visible Crow’s feet wrinkles, moderate skin slackness and dull complexion .

### Interventions
The active intervention is a food supplement containing Prolastine, while the placebo contains the same excipients without the active ingredient. A restricted randomization list will be generated by an independent technician using the appropriate algorithm ("Wei'surn") of the PASS 11 software (PASS, LLC. Kaysville, UT, USA) and stored in a secure location. The Principal Investigator or designated personnel will dispense the products according to the generated randomization list: half of the subjects will be supplied with the active product, while the other half with the placebo. The study will be double-blind, meaning that subjects, Principal Investigator and collaborators are kept masked to products assignment. The products will be supplied in the same packaging with no obvious differences between them. Subjects take the assigned treatment for 84 days ± 2 days as follows: two capsules per day in the morning, with a glass of water, during breakfast.

### Intervention Type
Supplement

### Primary outcome(s)
1. Skin elasticity and firmness measured using a cutometer at baseline and after 28 and 84 days

2. Wrinkle depth measured using Primos 3D at baseline and after 28 and 84 days

3. Skin smoothness (Ra parameter) measured using Primos 3D at baseline and after 28 and 84 days

4. Skin moisturization measured using a corneometer at baseline and after 28 and 84 days

5. Skin radiance (gloss parameter) measured using a spectrophotometer/colorimeter CM 700D at baseline and after 28 and 84 day

6. skin wrinkledness, tonicity, moisturization and radiance measured using clinical internal scales at baseline and after 28 and 84 day

### Key secondary outcome(s)
1. Dermal fibres analysis measured using line-field confocal optical coherence tomography (LC-OCT) at baseline and after 84 days

2. Efficacy perceived and the pleasantness of the product measured using a self-evaluation questionnaire at 28 and 84 days

### Completion date
21/08/2026

## Eligibility

### Key inclusion criteria
1. Good general health
2. Caucasian ethnicity
3. Female sex
4. Age between 45 and 65 years old (extremes included)
5. Subjects with subjects with phototype II-IV (according to Fitzpatrick scale)
6. Subjects presenting visible Crow's feet wrinkles, moderate skin slackness and dull complexion

7. Subjects who have not been recently involved in any other similar study (evaluation is performed case by case by the experimenter but at least 1 month must be elapsed between a previous study on food supplement)
8. Subjects registered with health social security or health social insurance
9. Subjects having signed their written the Informed Consent Form (ICF) and Privacy Policy for their participation in the study
10. Subjects able to understand the language used in the investigation centre and the information given
11. Subjects able to comply with the protocol and follow protocol constraints and specific requirements
12. Willingness to intake during all the study period only the product to be tested
13. Willingness not to use similar products that could interfere with the product to be tested (e. g. antiaging oral/topic products)
14. Willingness to not vary the normal daily routine (i.e. lifestyle, physical activity, diet etc.)
15. Subjects under effective contraception (oral/not oral) if women of childbearing potential; not expected to be changed during the trial
16. Willingness to avoid direct sun to face during the duration of experiment
17. Willingness to not use tanning beds or other light therapies to face for duration of experiment
18. Willingness to no use of fillers, botox, or lasers during experiment

## Healthy volunteers allowed
Yes

## Age group
Mixed

## Lower age limit
45 Years

## Upper age limit
65 Years

## Sex
Female

## Total final enrolment
66

## Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
2. Subject is taking part or planning to participate to another clinical study in the same or in another investigation centre
3. Subject who is deprived of freedom by administrative or legal decision or under guardianship
4. Subject admitted in a sanitary or social facilities
5. Subject who is planning an hospitalization during the study
6. Subjects under treatment with food supplements which could interfere with the functionality of the product under study (e.g., supplements containing collagen peptides, hyaluronic acid, antioxidants compound or anti-inflammatory botanical extracts)
7. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (if women of childbearing potential)

8. Subject has started or changed estrogen-progesterone contraception or hormonal treatment, within the 3 months prior to the study or foreseeing it for the duration of the study
9. Subject having an acute, chronic or progressive diseases (e.g. sever atopic dermatitis, psoriasis) liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
10. Subjects under radiotherapy, chemotherapy at any time
11. Subject having a skin condition liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
12. Pharmacological treatments (topic or systemic) known to interfere with skin metabolism /physiology
13. Subjects under locally pharmacological/non-pharmacological treatment applied on the skin area monitored during the test
14. Subject with known or suspected sensitization to one or more test formulation ingredients
15. Subjects considered as not adequate to participate to the study by the investigator
16. Adult protected by law (under control or hospitalized in public or private institutions for reasons other than research, or incarcerated)
17. Subjects not able to communicate or cooperate with the investigator for problems related to language, mental retardation or impaired brain function.
18. Subjects who have used tanning beds or direct sun to the face in the previous 4 weeks
19. Subjects who have used fillers or botox to facial areas in the past 4 or 6 months

### Date of first enrolment
13/04/2026

### Date of final enrolment
08/05/2026

## Locations

### Countries of recruitment
France

Italy

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# Sponsor information

**Organisation**
SAS COPALIS Industrie

# Funder(s)

**Funder type**

**Funder Name**
SAS COPALIS Industrie

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not expected to be made available

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol file | version 1.0 | 16/03/2026 | 07/07/2026 | No | No |