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Evaluation of the efficacy of Phospholipids-based supplementation of Centella in improving face skin contitions

Submission date	Recruitment status	[X] Prospectively registered
20/01/2026	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/01/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/01/2026	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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Additional identifiers

Complife Italia Study no
IT0006560/25

Study information

Scientific Title
Evaluation of the efficacy of Phospholipids-based supplementation of Centella in improving face skin conditions: a double-blind, placebo-controlled, randomized, clinical-instrumental study

Acronym
CentellaSuppSkin

Study objectives
The aim of the study is to evaluate the efficacy of centella Phospholipids (Centella Phytosome TM) in improving face skin conditions, in subjects showing dry face skin, lack of skin elasticity and firmness and showing mild to moderate wrinkles in the crow's feet area. In addition, the pleasantness and perceived efficacy of the product are investigated through subjects' self-assessments.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/11/2025, Comitato Etico Indipendente per le Indagini Cliniche Non Farmacologiche (Via XX Settembre 30/4, Genova (GE), Genova, 16121, Italy; +39 105454842; a. scudieri@studinonfarmacologici.it), ref: 2025/19

Primary study design
Interventional

Allocation

Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment, Efficacy

Study type(s)

Health condition(s) or problem(s) studied
Healthy volunteers showing dry face skin, lack of skin elasticity and firmness and showing mild to moderate wrinkles in the crow’s feet area

Interventions
The active intervention is a food supplment containg Centella Phytosome™. The formulation contains a dry extract of Centella asiatica (L.) Urban (leaves) combined with sunflower lecithin, while the placebo intervention contains the same excipients without the active extract. Both the active and the placebo products are used as follows: one capsule per day intake in the morning after breakfast with a little water.
Half of the test subjects will be randomized to receive the test product and half of the test subjects will be randomized to receive the placebo product. A restricted randomization list will be created using PASS 2008 (PASS, LLC. Kaysville, UT, USA) statistical software running on Windows Server 2008 R2 Standard SP1 64-bit Edition (Microsoft, USA) by a biostatistician and stored in a safe place.
The randomization sequence will be stratified using “Efron’s biased coin” algorithm with a 1:1 allocation ratio. The allocation sequence will be concealed from the in-site study director in sequentially numbered, opaque, and sealed envelopes, reporting the unblinded treatment allocation (based on subject entry number in the study). The A4 sheet reporting the unblinded treatment will be folded to render the envelope impermeable to intense light. A masked allocation sequence will be prepared for the staff delivering the intervention based on the subject entry number in the study.
During the screening visit, the Principal Investigator evaluates the subject’s eligibility to participate in the study, and informs the participants about the trial procedures, potential risks, and expected benefits.Only those who provide written informed consent are enrolled.
The participants are then supplied with the active or the placebo product based on their entry number in the study . All measurements and assessments are performed using minimally invasive procedures. The total study duration is 84 days, with intermediate evaluation at 28 days.

Intervention Type
Supplement

Primary outcome(s)
1. Skin elasticity measured using Cutometer® (Courage + Khazaka electronic GmbH) method (suction and elongation) at baseline and after 28 and 84 days.

2. Skin profilometry measured using Primos CR-SF (Canfield Scientific) 3D imaging (fringe projection) at baseline and after 28 and 84 days.

Key secondary outcome(s))
1. Epidermis thickness and dermal fiber analysis measured using Line field Confocal Optical Coherence Tomography (LC-OCT) technology (DAMAE Medical) at baseline and after 28 and 84 days.

2. In situ evaluations measured using the cytokine dosage (ELISA) and FRAP (Ferric reducing anti oxidant potential) assay on skin strippings (stratum corneum) taken by Corneofix® (Courage + Khazaka electronic GmbH) at baseline and after 84 days.

3. Personal opinion on the tested product measured using self-assessment questionnaire at after 28 and 84 days.

4. Evaluation of the “younger skin” effect measured using mean value of periocular wrinkle depth variation at baseline and after 28 and 84 days.

Completion date
29/05/2026

Eligibility

Key inclusion criteria
1. Good general health.
2. Caucasian ethnicity.
3. Female sex.
4. Age between 45 and 60 years old (extremes included).
5. Subjects with dry face skin, lack of skin elasticity and firmness and showing mild to moderate wrinkles in the crow’s feet area.
6. Subjects who have not been recently involved in any other similar study (evaluation is performed case by case by the Investigator but at least 1 month must be elapsed between a previous study on food supplement).
7. Subjects registered with health social security or health social insurance.
8. Subjects having signed their written the Informed Consent Form (ICF) and Privacy Policy for their participation in the study.
9. Subjects able to understand the language used in the investigation centre and the information given.
10. Subjects able to comply with the protocol and follow protocol constraints and specific requirements.
11. Willingness to use during all the study period only the product to be tested.
12. Willingness not to use similar products that could interfere with the product to be tested (e. g. antiaging oral/topic products).
13. Willingness to not vary the normal daily routine (i.e. lifestyle, physical activity, diet etc.).
14. Subjects under effective contraception (oral/not oral) if women of childbearing potential; not expected to be changed during the trial.

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
45 years

Upper age limit
60 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria.
2. Subject is taking part or planning to participate in 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 sanitary or social facilities.
5. 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, antioxidant compounds or anti-inflammatory botanical extracts).
6. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (if women of childbearing potential).
7. 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.
8. Subject having acute, chronic or progressive diseases (e.g., severe 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.
9. Subjects under radiotherapy or chemotherapy at any time.
10. 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.
11. Pharmacological treatments (topical or systemic) known to interfere with skin metabolism /physiology.
12. Subjects under locally pharmacological or non-pharmacological treatment applied on the skin area monitored during the test.
13. Subject with known or suspected sensitization to one or more test formulation ingredients.
14. Subjects considered not adequate to participate in the study by the Investigator.
15. Adult protected by law (under control or hospitalized in public or private institutions for reasons other than research, or incarcerated).
16. Subjects not able to communicate or cooperate with the Investigator due to language problems, mental retardation, or impaired brain function.

Date of first enrolment
26/01/2026

Date of final enrolment
30/01/2026

Locations

Countries of recruitment
Italy

Study participating centre
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27028

Sponsor information

Organisation
INDENA S.P.A

Funder(s)

Funder type

Funder Name
INDENA S.P.A.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available