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Evaluation of the anti-aging efficacy of a dietary supplement on facial skin

Submission date	Recruitment status	[_] Prospectively registered
24/03/2026	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/04/2026	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/09/2026	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator

Contact name
Dr Enza Cestone

Contact details
Via Monsignor Angelini 21, San Martino Siccomario (PV) 27028 - Italy
Pavia
Italy
27100
+39 38225504
info@complifegroup.com

Type(s)
Scientific, Public

Contact name
Dr Fabiola Giovanna Mestanza Mattos

Contact details
Viale Indipendenza, 11, Pavia (PV)
Pavia
Italy
27100
+39 38225504
fabiola.mestanza@complifegroup.com

Additional identifiers

Clinical Study Protocol Number
EC_PIT0000339/25 ver.00 of 06/02/2026

Study Code_Order
H.E.HU.TE.NRF00.180.00.00_IT0000771/26

Study information

Scientific Title
Placebo-controlled clinical and instrumental evaluation of the anti-aging efficacy of a dietary supplement on facial skin

Study objectives
The primary objective of this study is to evaluate the anti-aging efficacy of the product. The secondary objective of this study is to evaluate the efficacy of the product in improve skin condition.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/03/2026, International Ethics and Integrity Committee (Via Per Garbagnate 61, Lainate (MI), Lainate, 20045, Italy; +39 3783037302; secretariat@ieicomittee.com), ref: Rif. IC0016 A

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 subjects exhibiting moderate clinical signs of skin aging, such as dark spots and wrinkles or fine lines in the crow’s feet area, nasolabial wrinkles and frontal wrinkles.

Interventions

The investigational products are food supplements provided as capsules containing Nutroxsun®, a standardized blend of Citrus paradisi and Rosmarinus officinalis extracts, administered at two different dosages. The high-dose formulation provides 250 mg of Nutroxsun®, while the low-dose formulation provides 100 mg of Nutroxsun®. The placebo contains the same excipients without the active ingredient. All products are supplied as identical capsules with the same shell components.
A restricted randomization list will be generated by an independent technician using the appropriate algorithm (“Wei’s urn”) 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: 60 subjects will receive the high-dose active product, 60 subjects the low-dose active product, and 60 subjects the placebo.
The study will be double-blind, meaning that subjects, the Principal Investigator and collaborators are kept masked to product assignment. The products will be supplied in the same packaging with no obvious differences between them.
Subjects will take the assigned treatment for 84 days ± 2 days as follows: one capsule per day, 30 minutes before or after breakfast.
To standardize the skincare routine during the study, subjects will receive a neutral base facial cream, which will replace their usual day and night facial creams throughout the study period. Participants will be instructed not to apply the cream on the morning of scheduled study assessments. Subjects will also be asked to maintain their usual dietary habits, avoid additional dietary supplements that could interfere with the study outcomes, and minimize unprotected exposure to sunlight or other UV sources during the study period.

Intervention Type

Supplement

Primary outcome(s)

1. Quantitative decrease in wrinkle depth in the crow's feet, nasolabial, and forehead areas measured using Primos-CR SF (Canfield Scientific Europe, BV, Utrecht, Netherlands) at baseline and after 14, 28, 56 and 84 days

2. Increase in gross or overall elasticity (R2 parameter) measured using Cutometer®MPA 580, Courage+Khazaka, electronic GmbH at baseline and after 28, 56 and 84 days of product use

3. Increase in skin distensibility (R0 parameter) measured using Cutometer®MPA 580, Courage+Khazaka, electronic GmbH at baseline and after 28, 56 and 84 days of product use

4. Increase in net elasticity (R5 parameter) measured using Cutometer®MPA 580, Courage+Khazaka, electronic GmbH at baseline and after 28, 56 and 84 days of product use

Key secondary outcome(s)

1. Improvement in water content (hydration) in the stratum corneum measured using Corneometer® at baseline and after 14, 28, 56 and 84 days of product use

2. Increased radiance (Gloss) measured using spectrophotometer/colorimeter CM-700D (Konica-Minolta) at baseline and after 14, 28, 56 and 84 days of product use

3. Reduced intensity of dark spots (ITA° value) measured using spectrophotometer /colorimeter CM-700d (Konica Minolta) at baseline and after 28, 56 and 84 days of product use

4. Increased density and thickness of the dermis measured using DUB SkinScanner System (22 MHz) and Ultrascan UC 22 (22 MHz,Courage + Khazaka) at baseline and after 28, 56 and 84 days of product use

5. Improvement in fiber density and anisotropy of the fiber network measured using Line field Confocal Optical Coherence Tomography (LC-OCT) technology at baseline and after 84 days of product use (on 20 Caucasian subjects per group)

6. Reduction of reactive oxygen metabolites (d-ROMs) in capillary blood measured using Free Radical Analytical System (FRAS 5) at baseline and after 84 days of product use (on Caucasian subjects only)

7. Increase in skin antioxidant potential measured using Ferric Reducing Antioxidant Power (FRAP) assay in tape-stripping samples at baseline and after 84 days of product use (on Caucasian subjects only)

8. Efficacy perceived and the pleasantness of the product measured using self-evaluation questionnaire (polytomous question with four possible answers) at 28, 56 and 84 days of product use

Completion date
11/09/2026

Eligibility

Key inclusion criteria
1.Healthy female subjects
2.Subjects of Caucasian and Asian (10% of the panel) ethnicity
3.Subjects aged between 35 and 65 years (extremes included, for Asian subjects the upper age limit may be extended by up to 5 years to ensure eligibility based on the inclusion criteria)
4.Subjects who exhibit moderate clinical signs of skin aging, such as dark spots and wrinkles or fine lines in the crow’s feet area, nasolabial wrinkles and frontal wrinkles
5.Subjects registered with national health service
6.Subjects certifying the truthfulness of the personal data disclosed to the Principal Investigator or designated personnel
7.Subjects able to understand the language used in the investigation centre and the information given by the Principal Investigator or designated personnel
8.Subjects able to respect the instructions given by the Principal Investigator or designated personnel as well as able to respect the study constraints and specific requirements
9.Subjects who commit not to change their daily routine or lifestyle during the study
10.Subjects on stable pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) for at least one month without any changes expected or planned during the study
11.Subjects informed about the test procedures who have signed a consent form and privacy agreement

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
35 Years

Upper age limit
70 Years

Sex
Female

Total final enrolment
180

Key exclusion criteria
1.Subjects who do not meet the inclusion criteria
2.Subjects with any acute, chronic, or progressive disease or condition that may interfere with the study data or that the Principal Investigator considers dangerous to the subject or incompatible with the requirements of the study
3.Subjects participating or planning to participate in other clinical trials
4.Subjects who participated in a similar study without respecting an adequate washout period (at least one month)
5.Subjects that have food intolerances or food allergies to ingredients of the study product
6.Subjects under pharmacological treatments that are considered incompatible with the study requirement by the Principal Investigator
7.Subjects who are currently using food supplement(s) and/or products with the same activity as the study product, or who haven't observed an adequate washout period (at least one month)
8.Subjects admitted to a health or social facility
9.Subjects planning a hospitalization during the study
10.Subjects not able to be contacted in case of emergency
11.Subjects deprived of freedom by administrative or legal decision or under guardianship
12.Subjects who have or have had a history of alcohol or drug addiction
13.Subjects with eating disorders (i.e. bulimia, psychogenic eating disorders, etc.)
14. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential)

Date of first enrolment
23/03/2026

Date of final enrolment
06/05/2026

Locations

Countries of recruitment
Italy

Study participating centre
Complife Italia
Via Monsignor Angelini 21, San Martino Siccomario
Pavia
Italy
27028

Sponsor information

Organisation
MONTELOEDER S.L.

Funder(s)

Funder type

Funder Name
MONTELOEDER S.L.

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			24/03/2026	No	No