

Evaluation of a mix of plant-derived extracellular vesicles for skin ageing in healthy women aged 45–65 years

Submission date 16/07/2026	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 07/08/2026	Overall study status Ongoing	☐ Statistical analysis plan
		☐ Results
Last Edited 07/08/2026	Condition category Skin and Connective Tissue Diseases	☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Skin ageing is a natural process that becomes more evident with age due to changes in skin structure and function. Reduced collagen production, loss of elasticity, decreased skin hydration, and increased oxidative stress contribute to the appearance of wrinkles, dull skin, and other visible signs of ageing. Plant-derived extracellular vesicles are naturally occurring nanoparticles isolated from fruits and vegetables that contain antioxidants and other bioactive compounds which may support skin health. This study aims to evaluate whether daily supplementation with a food supplement containing a mix of plant-derived extracellular vesicles (ExoComplex® Longevity) can improve skin ageing parameters in healthy women aged 45–65 years compared with placebo.

Who can participate?

Healthy women aged 45–65 years with visible signs of skin ageing, including dull and tired-looking skin, who are willing to provide written informed consent and comply with the study procedures will be eligible to participate.

What does the study involve?

Participants will be randomly assigned to receive either ExoComplex® Longevity or a matching placebo in a double-blind study. The intervention will last for approximately three months. Skin assessments will be performed before treatment and during follow-up visits using non-invasive instrumental techniques. The main parameters evaluated will include skin hydration, transepidermal water loss, skin elasticity, collagen index, skin brightness, and overall skin appearance. Safety and tolerability will also be monitored throughout the study.

What are the possible benefits and risks of participating?

Participants may benefit from improvements in skin hydration, elasticity, and overall skin appearance, although these benefits cannot be guaranteed. The food supplement contains naturally derived ingredients and is expected to be well tolerated. Any adverse events or unexpected reactions occurring during the study will be carefully monitored and recorded.

Where is the study run from?

The study will be conducted at the Department of Pharmacy, University of Naples Federico II, Naples, Italy.

When is the study starting and how long is it expected to run for?

July 2026 to November 2026

Who is funding the study?

ExoLab Italia S.r.l. (Italy)

Who is the main contact?

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Study information

Scientific Title

Evaluation of a food supplement containing a mix of plant-derived extracellular vesicles compared with placebo on skin ageing parameters in healthy women aged 45–65 years: a randomized, placebo-controlled, double-blind clinical trial

Acronym

EXOSKIN

Study objectives

1. To evaluate the efficacy of a food supplement containing a mix of plant-derived extracellular vesicles (ExoComplex® Longevity) in improving skin ageing parameters in healthy women aged 45–65 years compared with placebo
2. To assess the effects of the intervention on skin hydration, transepidermal water loss, skin elasticity, collagen index, skin brightness and overall skin appearance using validated non-invasive instrumental techniques
3. To evaluate the safety and tolerability of daily supplementation with ExoComplex® Longevity throughout the study period by monitoring adverse events and participant compliance

Ethics approval required

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Ethics approval(s)

Approved 24/02/2026, Institutional Review Board Dipartimento di Farmacia Università degli Studi di Napoli Federico II (Via Domenico Montesano 49, Napoli, 80131, Italy; + 39 81678650; sonia.laneri@unina.it), ref: RIF. 026-F01

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Placebo

Assignment

Parallel

Purpose

Prevention, Supportive care

Study type(s)**Health condition(s) or problem(s) studied**

Age-related skin ageing in healthy women aged 45–65 years

Interventions

Participants will be randomly assigned to either the ExoComplex® Longevity group or the placebo group in a parallel-group, double-blind study. Randomisation will be performed using a computer-generated random sequence by an investigator not involved in the clinical trial, who will also be responsible for allocation concealment. The study product and placebo will be identified by colour-coded labels according to the randomisation list and accessible only to the independent investigator responsible for randomisation and allocation. The allocation code will remain concealed until completion of the study, data collection and statistical analysis.

The study product will be administered orally as one capsule daily for three months. Participants in both groups will undergo the same schedule of study visits and non-invasive skin assessments at baseline and during follow-up. Skin hydration, transepidermal water loss, collagen index, skin elasticity, skin brightness and overall skin appearance will be evaluated using validated instrumental methods. Safety and tolerability will be assessed throughout the study by monitoring adverse events and participant compliance.

Intervention Type

Supplement

Primary outcome(s)

1. Skin hydration measured using corneometry using the Corneometer® CM 825 (C+K electronic GmbH) at baseline, 1 month, 2 months and 3 months

Key secondary outcome(s)

1. Transepidermal water loss measured using the Tewameter® TM Hex (C+K electronic GmbH) at baseline, 1 month, 2 months and 3 months

2. Skin elasticity measured using the Cutometer® MPA 580 (C+K electronic GmbH) at baseline, 1 month, 2 months and 3 months

3. Skin collagen index measured using DermaScan Cortex Technology at baseline, 1 month, 2 months and 3 months

4. Skin brightness measured using the Skin-colorimeter® CL 400 (C+K electronic GmbH) at baseline, 1 month, 2 months and 3 months

5. Skin fatigue measured using clinical and instrumental evaluation according to the study protocol at baseline, 1 month, 2 months and 3 months

Completion date

15/11/2026

Eligibility

Key inclusion criteria

1. Healthy female volunteers
2. Age between 45 and 65 years
3. Presence of visible signs of skin ageing, including dull and tired-looking skin
4. Ability and willingness to provide written informed consent and comply with all study procedures

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

45 Years

Upper age limit

65 Years

Sex

Female

Total final enrolment

0

Key exclusion criteria

1. Pregnancy or breastfeeding
2. Known allergy or hypersensitivity to any component of the study product
3. Current dermatological disorders affecting the face
4. Use of systemic or topical treatments that may interfere with the study outcomes within the protocol-defined washout period
5. Participation in another clinical study within the previous 30 days
6. Any medical condition that, in the investigator's opinion, could interfere with study participation or interpretation of the results

Date of first enrolment

20/07/2026

Date of final enrolment

27/07/2026

Locations

Countries of recruitment

Italy

Sponsor information

Organisation

Exolab Italia S.r.l.

Funder(s)

Funder type

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available