

Clinical and instrumental study on the anti-ageing effects of creams with hyaluronic acid, with and without Vitamin C

Submission date 25/07/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/07/2025	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/07/2025	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aim

Skin ageing is a multifaceted process influenced by both intrinsic and extrinsic factors, resulting in visible changes such as wrinkles, loss of elasticity, uneven skin tone, and hyperpigmentation. Hyaluronic acid (HA) is widely recognized for its hydrating and structural support properties, while Vitamin C is known for its antioxidant and depigmenting effects. This study investigated the anti-ageing effect of two topical formulations containing Jalubalance® technology - HA delivered in Opuntia oil, with or without 1% Vitamin C.

Who can participate?

Women aged between 30 and 50 years with mild to moderate photoaging

What does the study involve?

Participants were assigned to apply either HA-only cream (Group A) or a HA + Vitamin C cream (Group B) twice daily. The primary outcome was the percentage of subjects who achieved an improvement of at least one point in the hyperpigmentation score from baseline to week 8. Additionally, the study aimed to evaluate and compare the effects of both treatments, with a particular focus on improvements in wrinkles, elasticity, hydration, and pigmentation.

What are the possible benefits and risks of participating?

Benefits: improvement in skin ageing parameters. There are no expected risks for the participants.

Where is the study run from?

Donne Dermatologhe Italia (Italy)

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

February 2025 to June 2025

Who is funding the study?

Cantabria Labs Difa Cooper (Italy)

Who is the main contact?

Dr Massimo Milani, massimo.milani@difacooper.com

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Clinical and instrumental evaluation of the anti-ageing effectiveness of a cream based on hyaluronic acid and a cream based on hyaluronic acid and Vitamin C: a prospective, multicenter, 8-week, parallel-group randomized study on 91 subjects

Study objectives

The addition of 1% Vitamin C in a face cream improves skin quality parameters

Ethics approval required

Ethics approval not required

Ethics approval(s)

Study design

Prospective multicenter 8-week parallel-group randomized study

Primary study design

Interventional

Study type(s)

Efficacy

Health condition(s) or problem(s) studied

Skin aging

Interventions

Patients were randomized in a 1:1 ratio and instructed to apply a cream formulated with red algae and Lactobacillus, enriched with Jalubalance® technology (high-concentration hyaluronic acid delivered through Opuntia oil) (HA-only cream, Group A), or to apply a cream that combines the Jalubalance® technology with 1% Vitamin C (HA-Vitamin C cream, Group B). The products were applied to the entire face twice daily (morning and evening) for 8 weeks, using 1.5 g of product per application (3 FTUs) on cleansed skin. A dedicated computer program was used to generate the randomization list.

Intervention Type

Other

Primary outcome(s)

1. The percentage of subjects who achieved an improvement of at least one point in the hyperpigmentation score from baseline to week 8
2. Glogau score and a clinical score that assessed four parameters (wrinkles, elasticity, skin uniformity, and hyperpigmentation) with a 4-point score for each item (ranging from 0 = no issue to 3 = severe issue) from baseline to week 8

Key secondary outcome(s)

1. Instrumental evaluation of treatment efficacy using the Digital Skin Moisture Meter, which measures skin hydration, sebum content, and skin elasticity, from baseline to week 8
2. VISIA® objective face sculptor analysis performed in a subgroup of 10 subjects from baseline to week 8

Completion date

01/06/2025

Eligibility**Key inclusion criteria**

1. Women with mild to moderate photoaging (Glogau score 1 or 2)
2. Age between 30 and 50 years

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

30 years

Upper age limit

50 years

Sex

Female

Total final enrolment

91

Key exclusion criteria

1. Pregnancy or breastfeeding
2. Allergy to components present in the products
3. Acute facial skin diseases

Date of first enrolment

01/02/2025

Date of final enrolment

01/04/2025

Locations

Countries of recruitment

Italy

Study participating centre

Donne Dermatologhe Italia

Piazza Della Repubblica N 1/a

Milan

Italy

20121

Sponsor information

Organisation

Cantabria Labs Difacooper

Funder(s)

Funder type

Industry

Funder Name

Cantabria Labs Difa Cooper

Results and Publications**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available due to the privacy of the patients involved

IPD sharing plan summary

Not expected to be made available