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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

Registration date
28/07/2025

Overall study status
Completed

Last Edited
28/07/2025

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Medical and other records

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/02/2025

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

Age group
Adult

Lower age limit
30 Years

Upper age limit
50 Years

Sex
Female

Target number of participants
Group A: 47, Group B: 44

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
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Sponsor information

Organisation
Cantabria Labs Difacooper

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Cantabria Labs Difa Cooper

Results and Publications

Publication and dissemination plan
Publication in a peer-reviewed journal

Intention to publish date
06/05/2026

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