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A high-protection sunscreen with natural ingredients helps reduce dark patches and signs of skin aging on the face

Submission date
24/10/2025

Recruitment status
No longer recruiting

Registration date
27/10/2025

Overall study status
Completed

Last Edited
09/02/2026

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Melasma is a common skin condition that causes dark patches on the face, especially in areas exposed to the sun. It's more noticeable in people with lighter skin and can be triggered or worsened by sunlight. Many current treatments can cause irritation, take a long time to work, or lead to the skin lightening too much, especially in people with darker skin. This study looked at whether a special sunscreen containing ellagic acid, niacinamide, and a plant extract called Polypodium Leucotomos could help improve melasma without these side effects.

Who can participate?
The study included Caucasian women aged 25 to 60 years who had melasma on their face for at least five months.

What does the study involve?
Participants used a fluid cream sunscreen with added ingredients thought to help with melasma. The study tracked how their skin responded over time, but there was no comparison group or placebo.

What are the possible benefits and risks of participating?
Using the sunscreen may help reduce melasma and prevent it from coming back, without causing harm or side effects.

Where is the study run from?
Cantabria Labs Difa Cooper (Italy)

When is the study starting and how long is it expected to run for?
January 2023 to July 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title

A 50+ sunscreen containing polypodium leucotomos extract, ellagic acid, and niacinamide reduces facial melasma and photoaging-related hyperpigmentation: a pilot clinical and confocal microscopy evaluation

Acronym
PIGMENT

Study objectives
The study aimed to evaluate the efficacy of a fluid emulsion with SPF 50+ containing ellagic acid, niacinamide, Fernblock®+ (Polypodium Leucotomos extract), and vitamin E in the prevention and treatment of melasma and photoaging, using in vivo confocal microscopy

Ethics approval required
Ethics approval not required

Ethics approval(s)

Study design
Pilot prospective open-label study with a total duration of three months followed by a three-month follow-up

Primary study design
Interventional

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
The use of a sunscreen 50+ containing polypodium leucotomos extract, ellagic acid and niacinamide in patients with melasma

Interventions
Patients were instructed to apply the product every morning and reapply it every two hours during sun exposure, for a period of 12 weeks. The study lasted three months, followed by a three-month follow-up phase. Participants attended three study visits: at baseline (T0), after 12 weeks of treatment (T1), and after 24 weeks for the follow-up evaluation (T2).

Intervention Type
Other

Primary outcome(s)
Evaluation of clinical efficacy through the Melasma Area Severity Index (MASI) at baseline (T0), after 12 weeks of treatment (T1), and after 24 weeks for the follow-up evaluation (T2). The MASI was calculated by evaluating three factors: area involved (A), darkness (D), and homogeneity (H), across four distinct regions: the forehead, right malar region, left malar region, and chin. The total score range is 0 to 48.

Key secondary outcome(s))

1. Abnormal pigment deposits are measured using in vivo confocal microscopy (CM) at baseline (T0), after 12 weeks of treatment (T1), and after 24 weeks for follow-up evaluation (T2)
2. Cytological characteristics relevant to melasma diagnosis and classification are measured using in vivo confocal microscopy (CM) at baseline (T0), after 12 weeks of treatment (T1), and after 24 weeks for follow-up evaluation (T2)

Completion date
01/07/2025

Eligibility

Key inclusion criteria
1. Caucasian women aged 25 to 60 years
2. Facial melasma present for at least 5 months

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit
60 years

Sex
Female

Total final enrolment
20

Key exclusion criteria
1. Presence of other facial disorders
2. Use of topical treatments within the two months preceding study initiation
3. Pregnancy or lactation

Date of first enrolment
20/02/2023

Date of final enrolment
07/12/2024

Locations

Countries of recruitment
Italy

Study participating centre
Università Federico II di Napoli
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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 will be available upon request from Dr. Massimo Milani (massimo.milani@difacooper.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/02/2026	09/02/2026	Yes	No