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 | Prospectively registered |
|---------------------------------|--|--|
| | | Protocol |
| Registration date 27/10/2025 | Overall study status Completed | Statistical analysis plan |
| | | Results |
| Last Edited | Condition category | Individual participant data |
| 24/10/2025 | Skin and Connective Tissue Diseases | [X] Record updated in last year |

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)

Contact information

Type(s)

Public, Scientific

Contact name

Dr Massimo Milani

ORCID ID

https://orcid.org/0000-0001-7559-1202

Contact details

Via Milano, 160 Caronno Pertusella Italy 21042 +39 29659031 massimo.milani@difacooper.com

Type(s)

Principal investigator

Contact name

Dr Alessia Villani

Contact details

Via Sergio Pansini, 5 Napoli Italy 80131 +39 817463762 alessia.villani@unina.it

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

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)

Αll

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

Study participating centre Università Federico II di Napoli

Via Sergio Pansini,5 Napoli Italy 80131

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?

Participant information sheet

Participant information sheet 11/11/2025 11/11/2025 No

Yes