ISRCTN15776551 https://doi.org/10.1186/ISRCTN15776551

Clinical investigation to evaluate the efficacy and safety of laser prototype device

Submission date
07/11/2025

Recruitment status
Recruiting

Registration date
14/11/2025

Overall study status
Ongoing

Last Edited
02/02/2026

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is looking at how well a laser device, called the Epilady, works to reduce dark spots (known as lentigo or age spots) on the hands and forearms. Researchers also want to see if using a special skin serum alongside the laser treatment makes the results even better. The goal is to find out how effective and safe these treatments are over a period of 84 days.

Who can participate?
The study is open to healthy women aged between 35 and 70 years old. To take part, they must have at least two visible dark spots on each hand or forearm. Women of all skin tones (Fitzpatrick skin types I to VI) are welcome.

What does the study involve?
Each participant will receive laser treatment once a week for 12 weeks. One side of their body (hand and forearm) will be treated with the laser only. The other side will be treated with the laser and then have a skin serum applied twice daily. Participants will also attend four evaluation visits on Day 0, Day 28, Day 56, and Day 84 to track progress and share feedback.

What are the possible benefits and risks of participating?
The potential benefits include a visible reduction in dark spots and improved skin appearance using a non-invasive treatment. Risks may include temporary skin reactions like redness, swelling, mild scabbing, or changes in skin color. Some discomfort during laser treatment is also possible.

Where is the study run from?
CIDP Ltée (Mauritius)

When is the study starting and how long is it expected to run for?
The study will take place between January and June 2026. Each participant will be involved for about three months.

Who is funding the study?
L'Oréal (France)

Who is the main contact?
The lead investigator is Dr. Gitanjali Petkar. You can contact her at: g.petkar@cidp-cro.com

Contact information

Type(s)
Public, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title

Clinical investigation to evaluate the efficacy and safety of laser prototype device followed by application of a topical formula on depigmentation of lentigo spots in healthy women participants

Acronym
EPI LASER

Study objectives
Primary objectives
To assess the efficacy of the Epilady investigational device, used with and without a topical depigmenting formula, in reducing the appearance of lentigo spots on the hands and forearms of healthy female participants over an 84-day period

Secondary objectives
1. To evaluate the tolerance of the Epilady investigational device following repeated use
2. To assess the safety of the combined use of the device and the active depigmenting formula
3. To illustrate treatment outcomes using standardized photography (e.g., VISIA CR)
4. To collect participant self-assessments related to treatment satisfaction and perceived skin improvements

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/01/2026, Ministry of Health and Wellness (Level 2 Nexsky Building, Ebene, 72201, Mauritius; +230 (0)201 2175; -), ref: -

Study design
Prospective open-label randomized intra-individual controlled clinical investigation

Primary study design
Interventional

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Dark spot

Interventions
Laser treatment with or without formula.

This study is an intra-individual randomized right/left study.
The right or left side will receive on-site laser treatment once a week for 3 months.
The other right or left side will receive on-site laser treatment once a week and the formula twice a day for 3 months.

Intervention Type
Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Prototype laser

Primary outcome(s)
Pigmentation intensity of lentigo spots as assessed by a clinical color chart (e.g., L'Oréal pigmentation scale) at baseline , D28, D56 an D84

Key secondary outcome(s))
1. Lentigines Global Improvement Scale (LGIS) score (0 : Completery clear to 6: worse) at D28, D56 an D84
2. Participant self-assessment of efficacy as assessed by questionnaire t baseline , D28, D56 an D84
3. Investigators assessed local tolerance (erythema, edema, dryness, etc.) at D0 (before treatment) and after each application of the device
4. Global tolerance as assess by investigator by the scale with 4 grades (1: very good to 4 :bad) at D28, D56 an D84
5. Assessment of all adverse events (AEs) and serious adverse events (SAEs) occurring during the clinical investigation to determine device-relatedness and severity, serving as a safety endpoint for the entire duration of the study

Completion date
17/06/2026

Eligibility

Key inclusion criteria
1. Healthy female participants aged between 35 and 70 years old at the time of inclusion.
2. All Fitzpatrick skin phototypes (I to VI) are eligible; groups I-II and V-VI should include at least one participant per group.
3. Presence of at least two solar lentigo (dark spots) on each hand or forearm, with each spot measuring less than 100 mm x 100 mm as assessed by the investigator.
4. Participant has read, understood, and accepted the constraints of the clinical investigation.
5. Participant has provided written informed consent to participate in the clinical investigation
6. Participant is able to understand the language used in the investigational site and comprehend the information provided.
7. Participants are cooperative and compliant, aware of the clinical investigation requirements and willing to adhere to the full duration of participation and follow-up visits, in line with the CIP requirements.
8. Women of childbearing potential must commit to using an effective contraceptive method throughout the clinical investigation period and for at least three months prior to the inclusion visit, with no changes during that time.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
35 years

Upper age limit
70 years

Sex
Female

Total final enrolment
40

Key exclusion criteria
1. Participants with dry or sensitive skin, as assessed by the investigator.
2. Participants who have used cosmetic products with exfoliating or astringent claims on the hands within 4 weeks prior to the baseline visit.
3. Participants who have used any home-use or professional low-level laser therapy (LLLT) or have participated in clinical studies involving LLLT within the 6 months preceding the baseline visit.
4. History of light-induced seizures or chronic migraine disorders.
5. History of photosensitivity or photoallergic reactions.
6. Presence of underlying dermatological conditions on the hands/forearms that, in the opinion of the investigator, could interfere with the clinical investigation assessments.
7. History of keloid scar formation.
8. A family history of melanoma in first- or second-degree relatives (parents or grandparents).
9. Presence of excessive moles, non-lentigo pigmented lesions, tattoos, scars, or irritated skin in the test area that could affect the validity of the investigation.
10. History of surgical procedures involving the areas designated for treatment.
11. Participants who have been exposed to or plan to be exposed to sunbathing or artificial UV sources (e.g., mountain sports, phototherapy, tanning salons) within 1 month before the clinical investigation start or during the clinical investigation period.
12. Use of suntan or self-tanning products within the 2 weeks preceding the baseline visit.
13. Change in cosmetic habits (e.g., moisturizers, skincare, shower gels) during the 2 weeks prior to baseline.
14. Use of any medications, topical treatments, skincare products, or aesthetic procedures listed in the CIP without observing the required wash-out periods, or unwillingness/inability to comply with those restrictions during the clinical investigation.
15. Participant who cannot be contacted by telephone in case of emergency.
16. Participant in an exclusion period or participating in another biomedical research clinical investigation (self-reported).
17. Intellectual/mental inability to follow clinical investigation instructions (if suspected) or incapacitation.
18. Participants working for the contract research organization (CIDP) in charge of this clinical investigation.

Date of first enrolment
19/01/2026

Date of final enrolment

17/06/2026

Locations

Countries of recruitment
Mauritius

Study participating centre
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Sponsor information

Organisation
L'Oréal (France)

ROR
https://ror.org/00nb3j622

Funder(s)

Funder type
Industry

Funder Name
L'Oréal

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	04/11/2025	10/11/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes