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Testing how well a new sunscreen can help prevent dark spots that appear after the skin gets irritated or inflamed

Submission date
11/06/2025

Recruitment status
No longer recruiting

Registration date
18/06/2025

Overall study status
Completed

Last Edited
17/06/2025

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 aims
Post-inflammatory hyperpigmentation (PIHP) of the skin is a well-known phenomenon occurring in all skin types but with an increased prevalence in pigmented skin. PIHP can be seen in a number of skin conditions such as acne, eczema and contact dermatitis, and also following external aggressions such as superficial aesthetic treatments (peeling, laser resurfacing), simple scratches, insect bites or exposure to irritant products.
The main objective of the current study is to evaluate the protective effect of a new sunscreen product on post-inflammatory hyperpigmentation.

Who can participate?
Healthy women and men between 20 and 50 years old with a known history of PIHP after intense sun exposure and Fitzpatrick phototypes IV or V

What does the study involve?
Participants will have to attend a total of 20 visits as follows:
1. A screening visit (between Day -21 and Day -1)
2. 19 evaluation visits (from Day 1 to Day 22, except Sundays)
Six test areas are delineated on the back and subjected to tape stripping. Sunscreen was applied to three areas (two stripped and one non-stripped), followed by UV and visible light exposures on four of the six areas. Daily product application continued (except Sundays) through Day 20. Clinical assessments, photographs, redness and pigmentation evaluation, skin colour measurements and tolerability evaluations are conducted at scheduled visits through Day 36.

What are the possible benefits and risks of participating?
Benefits: Sunscreen is safe and has a very high protection against UVB and UVA, which was confirmed in different studies.
Risks: Possible local intolerance effects. Stripping is a very superficial damage to remove stratum corneum and is completely reversible and does not leave any scars. Post-inflammatory pigmentation disappears within weeks/months if not exposed to the sun.
The overall benefit/risk ratio appears favourable.

Where is the study run from?
CPCAD (France)

When is the study starting and how long is it expected to run for?
August 2024 to December 2024

Who is funding the study?
ISDIN S.A. (Spain)

Who is the main contact?
Dr Catherine Queille-Roussel, catherine.queille-roussel@skinpharma.fr

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
Nil known

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2023-A02785-40

Study information

Scientific Title
Evaluation of the protective effect of a new sunscreen formulation using the post-inflammatory hyperpigmentation model

Acronym
PIHP

Study objectives
A cream providing a high solar UV protection is effective at preventing post-inflammatory hyperpigmentation (PIHP).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/05/2024, Comité de protection des personnes Ouest III (CHU La Milétrie - Bâtiment Vie la Santé - Entrée n° 4 1er étage, - 2 rue de la milétrie CS 90577, Poitiers, 86021, France; +33 (0)516604227; cpp-ouest3@chu-poitiers.fr), ref: 24.01501.000289

Study design
Monocentric investigator-masked randomized controlled study with intra-individual comparisons

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Post-inflammatory hyperpigmentation

Interventions
At Baseline (Day 1), each participant who fulfilled all inclusion/exclusion criteria was assigned a Randomization Number. This Randomization Number was dispensed in the chronological order of her/his inclusion in the trial and no number should be omitted or skipped. The date and time of randomization defined this number, independently of the SIN that was assigned at the Screening visit.

The randomization list was prepared by the Biometrics of the CPCAD using R software version 4.0.2 or higher (Foundation for Statistical Computing, Vienna, Austria 2012) by a person not participating in the performance phase of the study.

The randomization list allocated, for each participant, the type of area to a test area number (Z1 to Z6). The six test areas (Z1 to Z6) comprised:
1. Stripped, protected, and exposed
2. Stripped, protected and unexposed
3. Stripped, unprotected, and exposed
4. Stripped, unprotected and unexposed
5. Non-stripped, protected and exposed
6. Non-stripped, not protected and exposed

Participants will have to attend a total of 20 visits as follows:
1. A screening visit (between Day -21 and Day -1)
2. 19 evaluation visits (from Day 1 to Day 22, except Sundays)

The model of inflammation using skin stripping was used to induce PIHP. This model consists of removing successive layers of the stratum corneum by means of an adhesive tape; a technique long used in dermatological research to induce superficial epidermal damage that disrupts the cutaneous epithelial barrier and stimulates various biological responses in the skin. PIHP would appear on the unprotected exposed area (PIHP UV stimulated) and, to a small extent, on the unprotected unexposed area (PIHP inflammation stimulated).

After Minimal Erythemal Dose determination on Day 1, on Day 2, six 19 x 60 mm test areas (Z1–Z6) are delineated on the back and subjected to tape stripping as per group assignment. Sunscreen was applied to three areas (two stripped and one non-stripped) at 2mg/cm², followed by UV and visible light exposures on four of the six areas. Daily product application continued (except Sundays) through Day 20.

Clinical assessments, photographs, redness and pigmentation evaluation, skin colour measurements and tolerability evaluations are conducted at scheduled visits through Day 36.

Intervention Type
Other

Primary outcome measure
Skin color (Individual Typology Angle [ITA°], Delta L*, Delta a*, Delta b*, Delta E*) measured using Chromameter CR 400 on baseline, Day 3, Day 5, Day 8, Day 15, Day 22 and Day 36 and before any product application

Secondary outcome measures
1. Erythema is measured by clinical score on baseline, Day 3, Day 5, Day 8, Day 15, and before any product application
2. Pigmentation is measured by clinical score on baseline, Day 3, Day 5, Day 8, Day 15, and before any product application

Overall study start date
22/08/2024

Completion date
02/12/2024

Eligibility

Key inclusion criteria
1. Signed an informed consent form (ICF)
2. Healthy male or female aged 20 to 50 years inclusive with a known history of PIHP after intense sun exposure
3. Phototype IV or V according to the Fitzpatrick classification
4. Female of non-childbearing potential, defined as a woman without uterus and/or both ovaries, surgically sterile (at least 6 months prior to the Screening visit) or post-menopausal (at least 1 year post cessation of menses)
5. Female of childbearing potential who has been, in the opinion of the Investigator, using an approved method of birth control for at least 1 month prior to the Screening visit and agrees to continue adequate contraception during the entire study period. Reliable methods of contraception are:
5.1. Hormonal method or intrauterine device in use since at least 1 month prior to the Screening visit and during the investigation period
5.2. Bilateral tubal ligation since at least 3 months prior to the Screening visit
5.3. Barrier methods in use for at least 14 days prior to the Screening visit
5.4. Vasectomized partner
5.5. Sexual abstinence, defined as refraining from heterosexual intercourse for at least 3 months prior to the Screening visit and during the entire period of risk associated with the study products
6. Had not been exposed to UV radiation (tanning beds, phototherapy, and sunlight) on the whole body for at least two months before the screening visit and agreed to avoid exposure for the whole duration of the study
7. Agreed not to bathe (no baths or swimming) during the whole study period
8. Agreed not to apply cosmetic, medical, or aesthetic treatments out of the study protocol on the back during the whole study period
9. Affiliated to a health social security system (according to French Law)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
20 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
20

Total final enrolment
21

Key exclusion criteria
1. Female who was pregnant, parturient or breastfeeding
2. Female of childbearing potential who had a positive urinary pregnancy test at Day 1
3. Had a medical history/condition or was taking medication that could put him or her at undue risk or may have interfered with the study results
4. Had known or suspected allergies or sensitivities to any of the components of the study product
5. Had a recent history of (within the last 3 months) or with an active pityriasis versicolor
6. Excessive number of naevi, freckles, lentigines in test area site (middle back)
7. Had taken a systemic treatment, able to induce an abnormal response to UV, for more than 5 days during the month preceding inclusion (steroids, non-steroidal anti-inflammatories, insulin, anti-hypertensives, antibiotics such as quinolones, tetracyclines, thiazides and fluoroquinolones, and all other photosensitizing treatments), or any treatment capable of inducing an abnormal response to UV or VL (e.g., vitamin A derivatives, psoralen, aminolevulinic acid derivatives), or who planned to take these treatments during the study
8. Protected subject, as defined in the Articles of the French Public Health Code. Article 1121-7: person deprived of liberty by a judicial or administrative decision, or subject to psychiatric care, or person admitted to a health or social institution for purposes other than the research. Article 1121-8: adult person subject to a legal protection measure or unable to express his/her consent;
9. Unable to communicate with or cooperate with the Investigator
10. Currently participating in another clinical study, or who was in an exclusion period of another clinical study
11. Had received 6.000 euros indemnities for participation in clinical trials/investigations in the previous 12 months, including participation in the present study (in accordance with French Law)

Date of first enrolment
22/08/2024

Date of final enrolment
28/10/2024

Locations

Countries of recruitment
France

Study participating centre

CPCAD
151, route de St Antoine
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Isdin (Spain)

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Industry

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Funder(s)

Funder type
Industry

Funder Name
ISDIN S.A.

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date