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Evaluation of a sunscreen product compared with established reference products in outdoor conditions

Submission date
07/07/2022

Recruitment status
No longer recruiting

Registration date
11/08/2022

Overall study status
Completed

Last Edited
30/09/2022

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
The aim of this study is to provide evidence of how a new broad-spectrum sunscreen SPF50 performs in outdoor conditions of extreme solar exposure compared with established reference sunscreens established by the International Organization for Standardization in 2019 (ISO 24444: 2019).

Who can participate?
Caucasian healthy adult volunteers.

What does the study involve?
The study will take place in an outdoor facility in Mauritius between November 2021 and December 2021. Each participant will receive treatment with the broad-spectrum SPF50 sunscreen (investigational product) and 3 reference ISO products: P3 (SPF15), P5 (SPF30), and P8 (SPF50+). Each of the 4 products will be applied to one of 6 defined areas of the participants' backs, with the remaining 2 areas treated with no sunscreen. The products will all be applied at the same density.
The sunscreen-treated areas will be exposed to the sun for 2 or 3 hours (depending on their baseline skin color). The amount of Ultraviolet A (UVA) and Ultraviolet B (UVB) radiation that participants receive during this time will be measured. Participants' skin will be assessed after 24 hours and after 1 week.

What are the possible benefits and risks of participating?
This study was without direct benefit to the participant. There was a minimum risk predictable to subjects' health given that the composition of the test products only used known ingredients at safe concentrations. It was however considered that there was still a theoretical possibility of local skin reactions (such as allergic dermatitis or irritant dermatitis) and that sunburn on the test area could not be totally excluded given the high UV indexes. Subjects were instructed to contact the investigator site if any of those reactions occurred and they were followed up until the total resolution of the adverse event. In case of any adverse event after the study period, the subjects were requested to contact the investigator site to be examined by the

dermatologist investigator. The study investigator had to follow up on the evolution of the event and determine the relationship to the test product if applicable. The safety of the investigational product had been proved through previous studies as demonstrated in the safety declaration.

Where is the study run from?
ISDIN (Spain)

When is the study starting and how long is it expected to run for?
September 2021 to December 2021

Who is funding the study?
ISDIN (Spain)

Who is the main contact?
Mr Javier Bustos, javier.bustos@isdin.com

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
ISD-FTP-798-03-2021

Study information

Scientific Title
Evaluation of sun protective effect of a sunscreen product under outdoor conditions compared to SPF15, SPF30 and SPF50+. A randomized, double blind, intra-individual, single center clinical study in healthy subjects

Study objectives
Efficacy of a broad-spectrum SPF 50 sunscreen in comparison with other reference products in outdoor conditions

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/10/2021, IBL Life Ltd Ethics Committee (4th Floor, IBL House, Caudan Waterfront, 11307, Port Louis, Mauritius; +230 203 2000; iblinfo@iblgroup.com), ref: EC21-COS-067-1

Primary study design
Interventional

Study design
Double-blinded, single-center, within-subject randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Sunburn

Interventions
On day 1, participants will be assessed using calorimetry to calculate Individual Typology Angle (ITA). Then the investigational product and reference products will be applied to the back of the subjects on randomized defined areas between the scapula and the waist (6 areas per subject). Each area was treated with a different sunscreen: either the investigational product (sunscreen SPF 50), the standard reference products from ISO 24444:2019: P3 (SPF15), P5 (SPF30), and P8 (SPF50+), or no sunscreen (2 areas with no sunscreen, as positive and negative control). Application of the investigational product, as well as standard reference products, on the treated area, was done according to the randomization list. The tested areas were defined as healthy areas on the back. For safety reasons, the non-treated area was not blinded. Products were applied at 2 mg/cm².

The comparison will be performed under very high and extreme UV radiations conditions, in an outdoor conditions (at an outdoor facility in Mauritius between November 2021 and December 2021). The exposition time (2-3 h) of each subject corresponded to ITA° with an expected cumulative dose of approximately 100 to 250 mJ/cm² for the treated areas. For each subject the cumulative UVA and UVB doses will be recorded using a radiometer.

Participants will be assessed for clinical erythema 24 h (at 20 ±4 h) after exposure, clinical delayed pigmentation 1 week (on day 8 ±1 days) after exposure, and colorimetry performed at both 24 h and 1 week.

Intervention Type
Other

Primary outcome(s)

Photoprotective effect measured using an erythema grading scale (grades 0-5) for all investigational areas assessed by a trained evaluator at 24 h

Key secondary outcome(s)
1. Skin redness measured using a Chromameter CR-400 (Konica Minolta) to record L* (lightness), a* (redness), and ITA° (overall colour) for all investigational areas at baseline, 24 h, and 1 week
2. Skin lightness measured using a Chromameter CR-400 (Konica Minolta) to record L*, a*, and ITA° for all investigational areas at baseline, 24 h and 1 week
3. Evolution of the pigmentation compared to negative control measured using a pigmentation grading scale (grades 0-4) for all investigational areas assessed by a trained evaluator at 1 week
4. Safety and tolerance measured using incidence of adverse events recorded between baseline and 1 week

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Healthy subjects
2. Caucasian with Individual Typology Angle (ITA) ≥ 28°
2. Aged ≥18 and ≤55 years
3. Uniform skin color of the whole investigational area

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
65

Key exclusion criteria
1. Pregnant or breastfeeding
2. Have used a sunbed or have had intensive sun exposure to the investigational areas within the 3 months before inclusion

3. ITA <28°
4. Tanned or sunburned (erythema) back
5. Dermatological disorders affecting the investigational areas (e.g. presence of multiple nevi, freckles, excess hair or uneven skin tones, tattoo, vitiligo, photo-dermatological disorders)
7. History of abnormal response to sun
8. History of allergy, hypersensitivity, or any serious reaction to any cosmetic product
9. Any concomitant medical condition that the investigator judges may interfere with the study

Date of first enrolment
01/11/2021

Date of final enrolment
08/12/2021

Locations

Countries of recruitment
Mauritius

Study participating centre
CIDP Lyee
Biopark, Socota Phoenicia
Sayed Hoseen Road
Phoenix
Mauritius
73408

Sponsor information

Organisation
Isdin (Spain)

ROR
https://ror.org/04dg86p75

Funder(s)

Funder type
Industry

Funder Name
ISDIN

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Javier Bustos (Javier.bustos@isdin.com). Individual participant data (in the form of text, tables, figures, and appendices) that underlie the results reported in this article, after deidentification, will be available upon request after publication and ending 36 months after publication. The data sets are stored on spreadsheets and all appropriate requests for appropriate analysis and mechanisms will be considered.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/09/2022	30/09/2022	Yes	No