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Instrumental evaluation of the photo-protective and antiageing efficacy of a food supplement

Submission date
01/10/2019

Recruitment status
No longer recruiting

Registration date
03/10/2019

Overall study status
Completed

Last Edited
12/05/2020

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 objective of this study was to evaluate the efficacy and tolerance of SUN ISDIN in reducing the susceptibility to UVR exposure (erythema response of skin and lipoperoxides) and in improving ageing signs

Who can participate?
Subjects between 40 and 65 years old, showing clinical ageing sings and at least one dark spot on the face

What does the study involve?
Participants will take one capsule once a day in the morning: the capsule must be taken whole with plenty of liquid during the entire study. Skin condition will be assessed in a clinical assessment at baseline and after14, 28, 56 and 84 days product use

What are the possible benefits and risks of participating?
Benefits associated with product use and study participation are related to photo-protection action and improvement of skin appearance. During the study is possible that subjects would note a decrease in ageing signs.
The potential risks associated with the use of the product are related to both subjective and objective adverse events (AEs) (e.g. bloating, diarrhea, stomach ache). The occurrence of AEs related to individual susceptibility to specific ingredients in the product could be related to a biological phenomenon that is not avoidable. Potential risks are assumed to be from mild to moderate and are not expected to pose a risk to human health. Risks associated with the procedures involved in this study are judged as minor. All the measurements carried out are not invasive and no skin side effects are expected from the measurement process except for MED assessment. An erythema reaction is foreseen for the MED assessment procedure but, usually, this reaction disappears in a short time period and sometimes to a mild hyperpigmentation

Where is the study run from?
Complife Italia Srl, San Martino Siccomario, Italy

When is the study starting and how long is it expected to run for?
October 2018 for three months

Who is funding the study?
ISDIN S.A.

Who is the main contact?
Javier Bustos
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
E.HU.016-0030.01.005L

Study information

Scientific Title
Clinical-instrumental assessment of the sun protection and antiageing efficacy of a food supplement

Study objectives

SUNISDIN CAPSULES contains a combination of natural actives such as vitamins, carotenoids, selenium, green tea extract, Vitis Vinifera L. and Polypodium Leucotomos extract. The pool of vitamins such as Vitamin C, Vitamin E, Vitamin A together with Lutein, Green tea extract and Lycopene helps to fight free radicals reducing oxidative stress and support healthy cell bioenergetics and mitochondria function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/09/2018, Comitato Etico Indipendente per le Indagini Cliniche Non Farmacologiche (Via XX Settembre 30/4-16121 Genova, Italy; +39 (0)10 5454842; ssinf@messaggipec.it), ref: 2018 /10

Study design
Monocentric prospective open-label study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Antiaging and photoprotection

Interventions
One SUN ISDIN capsule is taken once a day in the morning: the capsules must be taken whole with plenty of liquid. Capsules are taken for 12 weeks.

Intervention Type
Supplement

Primary outcome measure
Photo-protective and antioxidant efficacy after 12 weeks use:
1. Skin moisturization
2. Skin radiance
3. Skin elasticity
4. Subjective evaluation
5. Tolerability

Secondary outcome measures
Skin condition assessed as above at baseline and after14, 28, 56 and 84 days use

Overall study start date
01/05/2018

Completion date
15/05/2019

Eligibility

Key inclusion criteria
1. Healthy female and male subjects (without any specific repartition)
2. Caucasian ethnicity
3. Phototype from I to III according to Fitzpatrick classification
4. Age between 40 and 65 years old
5. Showing clinical ageing signs
6. Showing at least one dark spot on face

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. Pregnant or breastfeeding women
2. Allergies or sensitivity to cosmetic products, toiletries, sunscreens, and/or topical drugs
3. Dermatological problems in the test area
4. Pharmacological treatments (both locally or systemically) known to interfere with the test product
5. Used self-tanning products for at least one month before study start

Date of first enrolment
02/10/2018

Date of final enrolment
12/01/2019

Locations

Countries of recruitment
Italy

Study participating centre
Complife Italia S.r.l
Via Angelini, 21
San Martino Siccomario
Italy
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Sponsor information

Organisation
ISDIN S.A.

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Sponsor type
Industry

ROR
https://ror.org/04dg86p75

Funder(s)

Funder type
Industry

Funder Name
ISDIN S.A.

Results and Publications

Publication and dissemination plan

The researchers intend to publish the study results in an international peer-reviewed indexed scientific journal.

Intention to publish date
10/10/2019

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.
Written informed consent from participants was obtained.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2020	12/05/2020	Yes	No