

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

<b>Submission date</b> 01/10/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/10/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/05/2020	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> 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 signs 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 after 14, 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  
Clinical Affairs Manager  
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## Contact information

**Type(s)**  
Public

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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(s)**

Photo-protective and antioxidant efficacy after 12 weeks use:

1. Skin moisturization
2. Skin radiance
3. Skin elasticity
4. Subjective evaluation
5. Tolerability

### **Key secondary outcome(s)**

Skin condition assessed as above at baseline and after 14, 28, 56 and 84 days use

### **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

27028

**Sponsor information**

## Organisation

ISDIN S.A.

## ROR

<https://ror.org/04dg86p75>

## Funder(s)

### Funder type

Industry

### Funder Name

ISDIN S.A.

## Results and Publications

### 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?
<a href="#">Results article</a>	results	01/02/2020	12/05/2020	Yes	No