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Efficacy of a food supplement in protecting the skin from the sun and reducing dark spots

Submission date
10/03/2024

Recruitment status
No longer recruiting

Registration date
08/04/2024

Overall study status
Completed

Last Edited
19/03/2024

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
The aim of this study is to find out whether an active food supplement intervention improves UV protection and has a whitening effect after the first intake and after 42 and 84 days of oral intake.

Who can participate?
Male and female participants aged from 28 to 52 years, with skin phototypes from I to III, showing dark spots (at least one spot with a minimum diameter of 3 mm) related to age, sun exposure or post-inflammatory hyperpigmentation

What does the study involve?
Participants are asked to attend clinic visits at screening and 24 hours (pilot study) after the first product intake and then after 42 and 84 days of food supplement intake. During the screening visit, the principal investigator will inform the participants about the procedure, risks, and benefits. Only participants giving their informed consent are enrolled in the study. The trial staff and the subjects then fix the date for the first visit. During the first visit, participants will answer all the questions on the medical questionnaires given by the principal investigator. The participants are then randomly allocated to use the active food supplement or the placebo products for 84 days.
To standardize the volunteer's cosmetic habits, a base face cream with Sun Protection Factor (SPF) without any cosmetic activity is provided to the subjects for use during the whole study period instead of their usual day/night face cream. All the measurements/assessments are carried out using non-invasive procedures. At each study check two visits are forseen: before and 24 hours after UV irradiation. The total duration of each visit is 30 minutes. The study duration is 84 days with one intermediate check at 42 days and a short-term visit 24 hours after the first product intake.

What are the possible benefits and risks of participating?
The potential benefits associated with the product use are improved skin protection against UV damage and skin conditions such as brown spots (related to age, sun exposure or post-inflammatory hyperpigmentation) and skin complexion.
Risks associated with the procedures involved in this study are judged as minor. All precautions

will be taken to ensure that the risk is the lowest possible. All the measurements carried out are minimally invasive and no side effects are expected from the measurement process. Due to the nature of the active ingredient volunteers blood pressure is monitored during the whole study period.

Where is the study run from?
Complife Italia S.R.L (Italy), laboratories of:
1. San Martino Siccomario (BI)
2. Biella (BI)

When is the study starting and how long is it expected to run for?
November 2023 to May 2024

Who is funding the study?
Activ'inside (France)

Who is the main contact?
Mrs Ileana De Ponti, ileana.deponti@complifegroup.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
.H.E.HU.HV.NWH00.060.41.00_IT0006474/23

Study information

Scientific Title
Short and long-term effect of a dietary supplement on UV protection and dark spots in healthy adults: a randomized, double-blind, placebo-controlled, parallel, clinical trial

Acronym

Sun&Spots

Study objectives
The study aims to assess the UV protection and the skin whitening efficacy of a food supplement on a panel of 66 subjects (to ensure that a minimum of 60 complete the study) after 42 and 84 days of intake. The principal aim is to evaluate the effects of the dietary supplement on UV protection.

The secondary aims are the evaluation of the efficacy in whitening brown spots (related to age, sun exposure or post-inflammatory hyperpigmentation) and the assessment of the short-term effects on UV protection 24h after UV exposure (pilot study on 10 subjects per arm). Moreover, product tolerability and volunteers' perceived efficacy by self-assessment questionnaire are evaluated.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/01/2024, Independent ethics committee for non-pharmacological clinical investigations (Via XX Settembre 30/4, Genova, 16121, Italy; +39 (0)10 5454842; ssinf@messaggipec.it), ref: 2023/18

Primary study design
Interventional

Study design
Multicenter stratified double-blind randomized placebo-controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Subjects with phototypes from I to III, showing hyperpigmentation, with at least one spot with a minimum diameter of 3 mm

Interventions
The active food supplement intervention is composed of grape seed extract, licorice root extract, grape pomace extract and coated vitamin C, while the placebo food supplement intervention is: maltodextrin. Both the active and the placebo products are used as follows: one capsule per day to be taken during breakfast with a glass of still water for 84 days.

To standardize the volunteer’s cosmetic habits, a base face cream with SPF without any cosmetic activity is provided for use during the whole study period instead of their usual day/night face cream.

Test subjects are randomized into two groups of 30 (33) subjects as follows: one group takes the active food supplement and one group takes the placebo food supplement,

A restricted randomization list is created using PASS 2008 (PASS, LLC. Kaysville, UT, USA) statistical software running on Windows Server 2008 R2 Standard SP1 64-bit Edition (Microsoft, USA) by a biostatistician and stored in a safe place. The randomization sequence was stratified

using “Efron’s biased coin” algorithm with a 1:1 allocation ratio. The allocation sequence was concealed from the in-site study director in sequentially numbered, opaque and sealed envelopes, reporting the unblinded treatment allocation (based on the subject entry number in the study). The A4 sheet reporting the unblinded treatment was folded to render the envelope impermeable to intense light. A masked allocation sequence was prepared for the staff delivering the intervention based on the subject entry number in the study.

Intervention Type
Supplement

Primary outcome(s)
UV protection evaluated by the assessment of the minimal erythemal dose (MED) at T0, T42 and T84. MED is performed by applying a series of UV exposures, using a model 601-300W solar simulator (Solar Light Co. Inc, Philadelphia, USA). Skin redness reaction after UV exposure is measured in the MED skin site using a colorimeter/spectrophotometer CM-700D (Konica Minolta). The parameter measured is the a* parameter of the CIELAB (1976) chromatic space. Digital pictures of the MED area were acquired using a digital camera at baseline (T0), 42 days (T42) and 84 days (T84).

Key secondary outcome(s)
1. Spots individual typology angle (ITA) measured using a spectrophotometer/colorimeter CM-700D (Konica-Minolta) at T0, T42, and T84 (days)
2. L* parameter (that defines the color brightness) on spots measured using a spectrophotometer/colorimeter CM-700D (Konica-Minolta) at T0, T42, and T84 (days)
3. Percentage of the skin area occupied by dark spots at T0, T42, and T84 (days), measured by means of a image analysis technique using the thresholding (segmentation) algorithm on RBX brown Visia®-CR pictures (Canfield Scientific).
4. Short-term effects of the dietary supplement on UV protection evaluated by the assessment of the minimal erythemal dose (MED). at the T0 and 24 h after the first product intake (pilot study performed on 10 subjects per arm). MED is performed by applying a series of UV exposures, using a model 601-300W solar simulator (Solar Light Co. Inc, Philadelphia, USA). Skin redness reaction after UV exposure is measured in the MED skin site using a colorimeter /spectrophotometer CM-700D (Konica Minolta). The parameter measured is the a* parameter of the CIELAB (1976) chromatic space. Digital pictures of the MED area acquired using a digital camera at baseline (T0) and at T24h.
5. Clinical evaluation of skin evenness complexion and whitening efficacy on Visia®-CR pictures (Canfield Scientific) using an improvement clinical scale (from 1: no variation to 4: remarkable improvement) at T42 and T84
6. Product safety assessed using adverse events recording throughout the study (T42 and T84)
7. Product acceptability and volunteers’ perceived efficacy assessed with a self-assessment questionnaire at T84

Completion date
31/05/2024

Eligibility

Key inclusion criteria
1. Healthy female (80%) and male (20%)
2. Caucasian ethnicity
3. Phototypes from I to III

4. Age between 28 and 52 years inclusive
5. Subject showing skin spots related to age, sun exposure or post-inflammatory hyperpigmentation, with at least one spot with a minimum diameter of 3 mm
6. Willingness to not consume during the study period products other than the test product as judged by the investigator,
7. Subjects registered with the National Health Service (NHS)
8. Subjects certifying the truthfulness of the personal data disclosed to the investigator
9. Subjects able to understand the language used in the investigation centre and the information given by the investigator
10. Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements
11. The pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) should be stable for at least one month without any changes expected or planned during the study
12. Commitment not to change the daily routine or the lifestyle
13. Subjects who have not been recently involved in any other similar study (at least one month of wash-out)
14. Subject under effective contraception (oral/not oral) therapy
15. Subjects who accept not to be exposed in an intensive way to UV rays during the whole study duration
16. Subject is aware of the study procedures and has signed an informed consent form and privacy information form.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
28 Years

Upper age limit
52 Years

Sex
All

Total final enrolment
66

Key exclusion criteria
1. Subject does not meet the inclusion criteria
2. Subjects participating or planning to participate in other clinical trials
3. Subjects deprived of freedom by administrative or legal decision or under guardianship
4. Subjects not able to be contacted in case of emergency
5. Subjects admitted to a health or social facility
6. Subjects planning a hospitalisation during the study

7. Subjects who participated in a similar study without respecting an adequate washout period
8. Subjects having an acute, chronic or progressive illness liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
9. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the investigator
10. Subjects having a skin disease or condition liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
11. Subject with known or suspected sensitization to one or more test formulation ingredients
12. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential)
13. Consumption of food supplement(s) and/or use of topical skincare products that have an influence on skin response to UV rays or dark spots (currently or within the past 4 weeks before the study)
14. Subjects accustomed to use tanning beds
15. Subjects taking medication with photosensitizing potential, drugs and/or dietary supplements able to induce skin coloring, corticoids, currently or during the month before the study

Date of first enrolment
24/01/2024

Date of final enrolment
29/02/2024

Locations

Countries of recruitment
Italy

Study participating centre
Complife Italia S.R.L
Via Monsignor Angelini, 21
San Martino Siccomario
Italy
27028

Study participating centre
Complife Italia S.R.L
Corso San Maurizio, 25
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Italy
13900

Sponsor information

Organisation
Activ'inside

Funder(s)

Funder type
Industry

Funder Name
Activ'inside

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository on Complife servers. A backup copy of the raw data will be also in a cloud-based backup server. Tables containing the raw data (output of the measurements) will be also included in the study report and shared with the study sponsor in a PDF file that is electronically signed. The raw data will be stored for a minimum period of 10 years on Complife servers. In the raw data tables, subjects are identified by means of a code generated by the Complife volunteer’s management software. The code is composed of a letter, four digits, and a letter. Access to the study's raw data is allowed only by the study director and the person designated by him to elaborate on the raw data. Elaboration of the raw data includes descriptive statistics (mean and standard error) and inferential analysis (data normality and statistical test).

IPD sharing plan summary
Stored in non-publicly available repository