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A study to evaluate the effect of Phenixun Shield® supplementation in UV radiation protection in Asian subjects

Submission date
17/07/2023

Recruitment status
No longer recruiting

Registration date
10/08/2023

Overall study status
Completed

Last Edited
25/07/2023

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
UV radiation can cause different acute and chronic effects on the skin. Phenixun Shield® is proposed to be a superior anti-oxidant supplement with unique photo-protective abilities because it contains multiple active ingredients that contribute to its superior skin protective efficacy through various molecular mechanisms. Previous in vitro studies have suggested the efficacy of this product in reducing UV damage, oxidative stress and cortisol production. The present study is designed to test the efficacy of Phenixun Shield® in various parameters that indicate the status of photoprotection and oxidative stress.

Who can participate?
Healthy non-smoker Asian female subjects aged between 25 and 55 years old (inclusive) with Fitzpatrick skin type II-IV

What does the study involve?
Participants will be randomly assigned to a once-daily Phenixun Shield® supplement or a placebo /dummy supplement for 8 weeks.

What are the possible benefits and risks of participating:
Possible benefits are an improvement in skin health. No risks are expected.

Where is the study run from?
INNOVATION LABO Sciences Co., Ltd (Japan)

When is the study starting and how long is it expected to run for?
June 2022 to June 2023

Who is funding the study?
INNOVATION LABO Sciences Co., Ltd (Japan)

Who is the main contact?
Dr Yuki Ikeda, development@innovationlabo.com (Japan)

Contact information

Type(s)
Scientific

Contact name
Dr Yuki Ikeda

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SE/INNOVATIONLABO 22-0528

Study information

Scientific Title
Double-blind placebo-controlled clinical study to evaluate the effect of supplementation with Phenixun Shield® during 8 weeks on skin protection immediately after exposure to ultraviolet radiation in Asian subjects

Acronym
PhenixunUV

Study objectives
Phenixun Shield® is more efficient than a placebo to decrease skin damage after exposition to UV radiation

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/12/2022, Japanese Society of Anti-Aging Nutrition (JAAN) (Ginza, Chuo-ku, Tokyo, 104-0061, Japan; +81 3 3552 5277; coordinator@jaan.jp), ref: ILOS22395-G133

Study design
Interventional double-blind placebo-controlled single-center randomized trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Prevention of skin Damage in health Asian patients

Interventions
Randomization: Block randomization is used to divide potential patients into m blocks of size 2n, randomize each block such that n patients are allocated to A and n to B then choose the blocks randomly. This method ensures equal treatment allocation within each block if the complete block is used.

Administration: Patients are asked to take Phenixun Shield® (250 mg in capsules) in the intervention group or placebo (dextrin 3g in a stick) in the control group orally in the morning before breakfast for 4 weeks. Products are to be taken directly in the mouth with a glass of water.

There are a total of 7 study visits. At each visit, the skin is exposed to ultraviolet light using a solar simulator that provides illumination reproducing natural sunlight.

The schedule of visits and measurements:
Visit 1, Week 0, Day 1: During the first visit, all baseline values are measured (hydration, transepidermal water loss (TEWL), erythema index, melanin index, plasma total antioxidant status (TAS), salivary cortisol levels, and faecal short-chain fatty acids (SCFA) levels). Skin Irradiation for the minimal erythema dose (MED) evaluation is done during the first visit.
Visit 2, Week 0, Day 2: MED evaluation will be done 24 hrs after skin Irradiation.
Visit 3, Week 2, Day 14: After 2 weeks of placebo/Phenixun intake, the inside of the right upper arm will be irradiated with 1.5 MED of UV.
Visit 4, Week 2, day 15: After 24 hours of 1.5 MED skin Irradiation, post-irradiation values of skin hydration, TEWL, erythema index, and salivary cortisol levels will be measured. These measurements will help to evaluate how well the test product supplementation helped to prevent UVR damage on the skin.
Visit 5, Week 4, Day 28: Skin hydration, TEWL, erythema index, and salivary cortisol level measurements will be repeated at week 4 to understand the efficacy of the test product in recovery after UV irradiation.
Visit 6, Week 8, Day 56: At week 8, outcome measures such as hydration, TEWL, erythema index,

melanin index, plasma TAS, salivary cortisol levels, and faecal SCFA levels will be evaluated again. Skin irradiation will be repeated for the end-of-study evaluation of MED.
Visit 7, Week 8, Day 57: MED evaluation will be repeated for end-of-study measurement.

Intervention Type
Supplement

Primary outcome(s)
The following primary outcome measures are assessed from baseline to post-irradiation (Visit 4, Week 2, day 15) and baseline to week 8:
1. Minimum erythema dosage measured using a mexameter
2. Skin hydration level measured using a corneometer

Key secondary outcome(s))
The following secondary outcome measures are assessed from baseline to week 8:
1. Erythema Index measured using a mexameter
2. Salivary cortisol level measured using an enzyme-linked immunosorbent assay
3. Melanin index measured using a mexameter
4. Plasma total antioxidant status (TAS) measured using an enzyme-linked immunosorbent assay
5. Faecal short-chain fatty acids (SCFA) levels using measured using a gas chromatography analysis

Completion date
20/06/2023

Eligibility

Key inclusion criteria
1. Healthy non-smoker Asian female subjects between aged 25 and 55 years (inclusive) old
2. Fitzpatrick skin type II - IV
3. Individuals of childbearing potential use an acceptable method of contraception throughout the study
4. Subjects must be stable on any medication they are taking for at least 30 days
5. Willing to give written informed consent and willing to comply with the trial protocol
6. Ability to understand the risks/benefits of the protocol
7. Subject should be available for the duration of the study period (8 weeks)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit

55 years

Sex
Female

Total final enrolment
60

Key exclusion criteria
1. Photosensitivity disorders
2. Condition and/or disease of the skin that the Investigator deems inappropriate for participation
3. Women who are nursing, pregnant, or planning to become pregnant during the study
4. Pre-existing or dormant dermatologic conditions which in the opinion of the Investigator could interfere with the outcome of the study
5. Regular consumption or application of any supplement (herbal, vitamin, etc)
6. Skin conditions including atopic dermatitis
7. Significant disease history of heart failure, dyslipidemia, diabetes, or uncontrolled hypertension
8. Risk of food allergy
9. Extreme skin condition changes caused by menstruation or irregular menstruation
10. Currently participating in another facial usage study or have participated in a clinical trial within 4 weeks prior to inclusion into the study
11. Planned surgeries and/or invasive medical procedures during the course of the study
12. Hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or who plan on starting, stopping, or changing doses of HRT or hormones for birth control during the study
13. Facial sunburn or excessively tanned facial skin or that are not willing to avoid daily sun exposure on the face and the use of tanning beds or sunless tanning products for the duration of the study
14. Currently taking or have taken oral or topical probiotics or antibiotics within the last 30 days
15. Subjects having a history of psychiatric disorder that may impair the ability of subjects to provide written informed consent
16. Patients who have completed participation in any other clinical trial during the past 3 month

Date of first enrolment
15/02/2023

Date of final enrolment
26/03/2023

Locations

Countries of recruitment
France

Study participating centre
Mayor In-vivo
1, place Marie Curie

Annecy
France
74000

Sponsor information

Organisation
INNOVATION LABO SCIENCES Co., Ltd

Funder(s)

Funder type
Industry

Funder Name
INNOVATION LABO SCIENCES Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Yuki Ikeda, development@innovationlabo.com. Individual participant data in an anonymous format will be shared upon publication of results and for a period of 2 years. Consent from participants is required and obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes