ISRCTN15458209 https://doi.org/10.1186/ISRCTN15458209

Evaluation of the benefits of berberine phospholipids supplementation in subjects with acne prone skin

Submission date	Recruitment status	[X] Prospectively registered
03/02/2026	Not yet recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/02/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
03/02/2026	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator

Contact name
Dr Gloria Roveda

Contact details
Via Monsignor Angelini 21, San Martino Siccomario (PV)
San Martino Siccomario
Italy
27028
+39 038225504
info@complifegroup.com

Type(s)
Scientific, Public

Contact name
Dr Eleonora Spartà

Contact details
Viale Indipendenza 11, Pavia (PV)
Pavia
Italy
27100

+39 038225504
eleonora.sparta@complifegroup.com

Type(s)
Scientific, Public

Contact name
Dr Anna Pelizzola

Contact details
Viale Indipendenza 11, Pavia (PV)
Pavia
Italy
27100
+39 038225504
anna.pelizzola@complifegroup.com

Additional identifiers

Complife Italia Study no
IT0006545/25

Study information

Scientific Title
A double-blind, randomized, placebo-controlled clinical-instrumental study to evaluate the benefits of berberine phospholipid supplementation in subjects with acne-prone skin

Acronym
BerbevisSuppAcne

Study objectives
The study aims to assess the effects of two actives concentrations of Berberine Phytosome™ (Berberine Phospholipids) in subjects with acne prone skin.
In particular, the study assesses the product's effectiveness in enhancing skin barrier function, reducing skin redness and sebum content, improving skin smoothness, and decreasing the number of both non-inflammatory and inflammatory lesions, while maintaining adequate skin hydration. In addition, the Investigator Global Assessment (IGA) of acne severity, the subjects' self-assessment, and acne-related quality of life will be assessed throughout the study.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/11/2025, Comitato Etico Indipendente per le Indagini Cliniche Non Farmacologiche (Via XX Settembre 30/4, Genova (GE), Genova, 16121, Italy; 010 5454842; a. scudieri@studinonfarmacologici.it), ref: 2025/20

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment, Efficacy and Pleasantness

Study type(s)

Health condition(s) or problem(s) studied
Healthy volunteers with acne prone skin

Interventions
The active intervention is a food supplement based on Berberine Phytosome™ (Berberine Phospholipids), standardized with a content of Berberine ranging from 28% to 34%; while the placebo intervention is composed exclusively of inert excipients and coating agents. Both the active and the placebo products are used as follows: the first group of subjects will take two tablets of the active product per day, one in the morning and one in the evening, both during meals, with a little water. The second group of subjects will take one tablet of the active product and one tablet of the placebo per day, one in the morning and one in the evening, both during meals, with a little water. The third group of subject will take two tablets of placebo, one in the morning and one in the evening, both during meals, with a little water.
Half of the test subjects will be randomized to receive the test product and half of the test subjects will be randomized to receive the placebo product. A restricted randomization list will be 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 will be stratified using “Efron’s biased coin” algorithm with a 1:1 allocation ratio. The allocation sequence will be concealed from the in-site study director in sequentially numbered, opaque, and sealed envelopes, reporting the unblinded treatment allocation (based on subject entry number in the study). The A4 sheet reporting the unblinded treatment will be folded to render the envelope impermeable to intense light. A masked allocation sequence will be prepared for the staff delivering the intervention based on the subject entry number in the study.
Participants are asked to attend clinic visits at screening and after 28, 56 and 84 days of product intake. During the screening visit, the dermatologist informs the participants about the trial procedure, risks, and benefits. Only participants giving their informed consent are enrolled in the study. The trial staff and the subjects fix then the date for the first check visit. The participants are then randomly allocated to use the Berbevis food supplement or the placebo product for 84 days. All the measurements/assessments are carried out using minimally invasive procedures. The study duration is 84 days with an intermediate check at 28 and 56 days.

Intervention Type
Supplement

Primary outcome(s)
1. Improve of the acne severity measured using the Investigator's Global Assessment (IGA) scale, a standardized 5-point system that rates the skin based on the number and type of acne lesions (blackheads, papules, pustules, and nodules) at baseline and after 28, 56 and 84 days.

Key secondary outcome(s))
1. Transepidermal water loss measured using Tewameter 300® (Courage+Khazaka, electronic GmbH) at baseline and after 28, 56 and 84 days.

2. Skin sebum content measured using Sebumeter® method (Sebumeter 815, Courage+Khazaka GmbH) at baseline and after 28, 56 and 84 days.

3. Skin redness (a* parameter) measured using dedicated software for image analysis (Image J) at baseline and after 28, 56 and 84 days.

4. Skin profilometry – Sa parameter related to skin smoothness in the cheek area measured using Primos CR-SF (Canfield Scientific) 3D imaging (fringe projection) at baseline and after 28, 56 and 84 days.

5. Skin moisturization measured using Corneometer® method at baseline and after 28, 56 and 84 days.

6. Evaluation of the number of non-inflammatory and inflammatory lesions measured using skin counting the acneic lesions at baseline and after 28, 56 and 84 days.

7. Digital macrophotography measured using Visia®-CR (Canfield Scientific) at baseline and after 28, 56 and 84 days.

8. Personal opinion on the tested product measured using self-assessment questionnaire at 28, 56 and 84 days.

9. Quality of life measured using quality of life questionnaire at baseline and after 28, 56 and 84 days.

Completion date
10/07/2026

Eligibility

Key inclusion criteria
1. Good general health
2. Caucasian ethnicity
3. Female sex
4. Age between 18 and 25 years old (subject with 18 and 25 years old can be included)
5. Subjects with acne prone skin, showing light to moderate acne prone skin with non-inflammatory lesions (comedones) and light inflammatory lesions (papules and pustules)
6. Subjects who have not been recently involved in any other similar study (evaluation is performed case by case by the Investigator but at least 1 month must be elapsed between a

previous study on food supplement)
7. Subjects registered with health social security or health social insurance
8. Subjects having signed their written the Informed Consent Form (ICF) and Privacy Policy for their participation in the study and a photograph authorization
9. Subjects able to understand the language used in the investigation centre and the information given
10. Subjects able to comply with the protocol and follow protocol constraints and specific requirements
11. Willingness to use during all the study period only the product to be tested
12. Willingness not to use similar products that could interfere with the product to be tested (e. g. products with anti-acne efficacy)*
13. Willingness to not vary the normal daily routine (i.e. lifestyle, physical activity, diet etc.)
14. Subjects under effective contraception (oral/not oral) if women of childbearing potential; not expected to be changed during the trial
* During the whole study period, subjects will use a defined cosmetic routine for face care, defined by the Costumer.

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
25 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
2. Subject is taking part or planning to participate to another clinical study in the same or in another investigation centre
3. Subject who is deprived of freedom by administrative or legal decision or under guardianship
4. Subject admitted in a sanitary or social facilities
5. Subject who is planning an hospitalization during the study
6. Subjects under treatment with food supplements which could interfere with the functionality of the product under study
7. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (if women of childbearing potential)
8. Subject has started or changed estrogen-progesterone contraception or hormonal treatment, within the 3 months prior to the study or foreseeing it for the duration of the study
9. Subject having an acute, chronic or progressive diseases (e.g severe atopic dermatitis, psoriasis) liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements

10. Subjects under radiotherapy, chemotherapy at any time
11. Subject having a skin condition liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
12. Pharmacological treatments (topic or systemic) known to interfere with skin metabolism /physiology (e.g. topical retinoids, topical antibiotics, oral antibiotics, isotretinoin)
13. Subjects under locally pharmacological/non-pharmacological treatment applied on the skin area monitored during the test (e.g. topical retinoids, topical antibiotics, isotretinoin)
14. Subject with known or suspected sensitization to one or more test formulation ingredients
15. Subjects considered as not adequate to participate to the study by the investigator
16. Adult protected by law (under control or hospitalized in public or private institutions for reasons other than research, or incarcerated)
17. Subjects not able to communicate or cooperate with the investigator for problems related to language, mental retardation or impaired brain function

Date of first enrolment
10/02/2026

Date of final enrolment
27/03/2026

Locations

Countries of recruitment
Italy

Study participating centre
Complife Italia srl
Via Monsignor Angelini 21, San Martino Siccomario (PV)
San Martino Siccomario
Italy
27028

Sponsor information

Organisation
INDENA S.P.A.

Funder(s)

Funder type

Funder Name

INDENA S.P.A.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available