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Effectiveness of a food supplement on acne prone skin on Asian population

Submission date
29/12/2023

Recruitment status
No longer recruiting

Registration date
26/01/2024

Overall study status
Completed

Last Edited
05/01/2024

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
Synbalance SRL (the sponsor of the study) is interested in assessing the effectiveness of a food supplement in improving skin conditions on subjects complaining of active acne skin, compared with a placebo formulation.

Who can participate?
Healthy women aged between 18 and 45 years, clinically show acne severity from 1 to 3 according to IGA scale

What does the study involve?
Participants are asked to attend clinic visits at screening (T0) and after 28 and 56 days of food supplement intake. Moreover a follow-up visit is foreseen 14 days after the last product intake (T70).
Subjects are randomly allocated to use the active food supplement or the placebo product for 56 days. There are two study groups:
1. The active study product,
2. The placebo formulation.
All the measurements/assessments are carried out using non-invasive procedures. The total duration of each visit is 30 minutes. The study duration is 70 days with two intermediate checks: after 28 days and 56 days of product(s) intake.

What are the possible benefits and risks of participating?
The potential benefits are an improvement of basal skin conditions (reduction of acne-related lesions with related improvement of skin complexion evenness, reduction of skin sebum content, increase of skin moisturization).
All the ingredients in the product formula are approved for their use in food/food supplements and are safe for use.
Potential risks (e.g. bloating, diarrhea, stomach ache) are assumed to be from mild to moderate and are not expected to pose a risk to human health. Risks associated with the product intake are considered from low to very low, in the absence of allergy/intolerances to product

ingredients; other ingredients in the product formula are commonly used in dietary supplements. All the measurements carried out are not invasive and no skin side effects are expected from the measurement process.

Where is the study run from?
Synbalance SRL (Italy)

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

Who is funding the study?
Synbalance SRL (Italy)

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

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
H.E.HU.AS.NAE00.060.08.00_IT0006453/23

Study information

Scientific Title
Double-blind, placebo-controlled clinical assessment of the efficacy of a food supplement tested on Asian subjects with acne-prone skin

Acronym
AcneCH

Study objectives
The study is aimed to assess the efficacy of a food supplement in improving skin appearance on adult Asian subjects affected by active acne after 28 and 56 days of product intake and after 14 days from the last product intake.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/12/2023, Independent Ethics Committee for Non-Pharmacological Clinical Investigations (Via XX Settembre 30/4, Genoa, 16121, Italy; +39 (0)10 5454842; ssinf@messaggipec.it), ref: 2023/15

Study design
Monocentric parallel-groups double-blind randomized placebo-controlled clinical study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Acne

Interventions
Active and placebo food supplement are manufactured according to the applicable national and international rules and regulation. All ingredients included in the active and placebo formula are approved for their use in food/food supplements.
All the active and the placebo products are used as follows: 1 capsule per day, preferably far from meal, for 56 days.

All participants will apply for all the study length a base cream with no cosmetic claim for face care, two times a day (morning and evening).

Participants are randomly into two groups of 32 subjects as follows:
1. 30 subjects (32 included) take the active study product
2. 30 subjects (32 included) take the placebo formulation

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 measure
1. Numbers of acne lesions (papules, pustules, open and closed comedones) at baseline (T0), after 28 days (T28) and 56 days (T56) of product intake and after 14 days of follow-up (T70).
2. Skin sebum content measured using Sebumeter 815 Courage+Khazaka GmbH, at baseline (T0), after 28 days (T28) and 56 days (T56) of product intake and after 14 days of follow-up (T70).
3. Skin moisturization measured using Corneometer CM825 Courage+Khazaka GmbH, at baseline (T0), after 28 days (T28) and 56 days (T56) of product intake and after 14 days of follow-up (T70).
4. Skin pH measured using SKIN pH-meter® 905 Courage+Khazaka GmbH, at baseline (T0), after 28 days (T28) and 56 days (T56) of product intake and after 14 days of follow-up (T70).
5. Digital pictures acquired by means of Visia®-CR (Canfield Scientific). at baseline (T0), after 28 days (T28) and 56 days (T56) of product intake and after 14 days of follow-up (T70).
6. Clinical evaluation of the improvment of skin complexion evenness (internal clinical scale) after 28 days (T28) and 56 days (T56) of product intake and after 14 days of follow-up (T70).
7. Clinical evaluation of the improvment of the erythemal state of the area interested by acne inflammatory lesions (internal clinical scale) after 28 days (T28) and 56 days (T56) of product intake and after 14 days of follow-up (T70).

Secondary outcome measures
1. Quality of life (“The Cardiff Acne Disability Index”) at baseline (T0), after 28 days (T28) and 56 days (T56) of product intake and after 14 days of follow-up (T70).
2. Product acceptability and volunteers’ perceived efficacy assessed with a self-assessment questionnaire at T56 and T70.
3. Product tolerability for all the study length assessed with a self-assessment questionnaire at T70

Overall study start date
01/11/2023

Completion date
10/02/2024

Eligibility

Key inclusion criteria
1. Healthy Asian female subjects
2. Aged between 18 and 45 (extremes included) years old
3. Subjects showing acne severity from 1 to 3 according to IGA scale
4. Subjects who have not been recently involved in any other similar study
5. Willingness to use during all the study period only the product to be tested
6. Subjects certifying the truthfulness of the personal data disclosed to the investigator
7. Subjects able to understand the language used in the investigation center and the information given by the investigator
8. Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements
9. 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
10. Commitment not to change the daily routine or the lifestyle
11. Subjects having signed their written Informed Consent form (ICF) and privacy form for their participation in the study and a photograph authorization.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
60

Total final enrolment
64

Key exclusion criteria
1. Subjects who do not fit the inclusion criteria;
2. Subjects with acute or chronic diseases able to interfere with the outcome of the study or that are considered dangerous for the subject or incompatible with the study requirements;
3. Subjects participating or planning to participate in other clinical trials;
4. Subjects deprived of freedom by administrative or legal decision or under guardianship;
5. Subjects not able to be contacted in case of emergency;
6. Subjects admitted to a health or social facility;
7. Subjects planning a hospitalisation during the study;
8. Subjects who participated in a similar study without respecting an adequate washout period;
9. 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;
10. Subjects with known hypersensitivity or allergy to one of the active ingredients;
11. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the investigator as for example medication with photosensitizing potential, drugs specific for acne treatment as isotretinoin or antibiotics, and/or food supplements and specific local therapy for acne treatment, currently or during the month before the study start;
12. 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;
13. Subjects that have shown allergies or sensitivity to cosmetic products, drugs, patch or medical devices;
14. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential);
15. Consumption of food supplement(s) containing probiotic and/or for skin/hair/nail care currently or within the past 12 weeks before the study.

Date of first enrolment
10/11/2023

Date of final enrolment
28/11/2023

Locations

Countries of recruitment
China

Study participating centre
Complife Beijing Testing Technology Co., Ltd
Beizhan North Street N.17, Room 902- Xicheng District
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Sponsor information

Organisation
SYNBALANCE SRL

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
SYNBALANCE SRL

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/03/2024

Individual participant data (IPD) sharing plan
Raw data will be stored 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 also be included in the study report and shared with the study sponsor in an electronically signed PDF file. 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 raw data is allowed only to 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