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Efficacy of a combined acne treatment

Submission date	Recruitment status	[_] Prospectively registered
03/11/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/11/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/08/2022	Skin and Connective Tissue Diseases	

Plain English summary of protocol

Background and study aims
Acne is a multifactorial inflammatory skin disease affecting the quality of life of acne-prone subjects. Several therapeutic approaches are currently used to counteract this condition, mostly having side effects. As acne development has been recently linked to skin and gut dysbiosis, acting on both aspects could represent an alternative and a promising approach to ameliorate the acne clinical signs.
This study aims to assess the efficacy of a combined treatment (a cosmetic product + a food supplement containing probiotics) in improving skin appearance on adult subjects affected by acne through the positive modulation of the microbiota. Such a hypothesis is tested by combining the intake of the probiotics mixture or the placebo together with two different cosmetic products, a basic cream containing 1% Ectoin or a commercially available cosmetic product (reference cosmetic product) specifically intended for a cosmetic treatment of acne.

Who can participate?
Healthy adults of both sexes, aged 18 to 50 years, with acne severity from 1 to 3 according to IGA scale

What does the study involve?
Participants will be randomly allocated in 4 groups to receive for 56 days: i) the basic cosmetic cream containing Ectoin plus the placebo food supplement; ii) the basic cosmetic cream containing Ectoin plus the active food supplement (containing the probiotics mixture); iii) the reference cosmetic product plus the placebo food supplement; iv) the reference cosmetic product plus the active food supplement.
Assessment of parameters was evaluated at the beginning of the study and after 28 and 56 days.

What are the possible benefits and risks of participating?
The benefits associated with product use are amelioration of acne clinical signs.
Risks associated with the product's intake/application are considered from low to very low, in absence of allergy/intolerances to products ingredients; other ingredients in the formula of the product are commonly used in dietary supplements. All the carried out instrumental measurements are not invasive and no skin side effects are expected from the measurement process.

Where is the study run from?
Complife Italia SRL (Italy)

When is the study starting and how long is it expected to run for?
February 2019 to July 2019

Who is funding the study?
This study was realized in the frame of SCIDA project funded by Lombardy Region, Italy (2014IT16RFOP012-POR FESR 2014-2020-Project ID226149).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
E.HU.111-0080.17.003L_2019-684

Study information

Scientific Title
Clinical assessment of a combined treatment targeting subjects with acne-prone skin

Study objectives
A combined treatment based on a cosmetic product and food supplement containing selected probiotics could ameliorate clinical signs of acne?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/04/2019; Independent Ethical Committee for Non-Pharmacological Clinical Study Trials (Società Scientifica Italiana per le Indagini Cliniche Non Farmacologiche, Via XX Settembre 30/4, 16121 Genova, Italy; +39(0)10 5454842; a.scudieri@studinonfarmacologici.it); ref: 2019/04

Primary study design
Interventional

Study design
Single-centre interventional double-blinded randomized placebo-controlled parallel-group clinical trial

Study type(s)
Treatment

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

Interventions
A double-blind, randomized, placebo/reference product-controlled clinical study was carried out on eighty subjects of both sexes, enrolled by a dermatologist according to specific inclusion /exclusion criteria; subjects were equally divided in the following 4 groups according to a randomization list previously generated using an appropriate statistic algorithm (“Wey’s urn”):
- Group 1 (G1): a basic cosmetic product containing 1% Ectoin + a placebo food supplement
- Group 2 (G2): a basic cosmetic product containing 1% Ectoin + an active food supplement (In&Out combined treatment)
- Group 3 (G3): a commercially available cosmetic product intended for cosmetic acne treatment available (cosmetic reference product)+ a placebo food supplement.
- Group 4 (G4): the cosmetic reference product + an active food supplement.

Subjects applied daily the cosmetics active/reference products and took one capsule of the active/placebo food supplement for 56 days.
Instrumental evaluations of skin parameters and dermatological assessments of the subjects' facial skin were carried out at baseline (T0), after 28 days, and after 56 days from the beginning of product use.

Intervention Type
Supplement

Primary outcome(s)
1. Sebum levels, measured by using the Sebumeter® method (Sebumeter 815, Courage+Khazaka GmbH) at t=0, T28 and T56.
2. Skin pH measured by SKIN pH-METER 905® (Courage + Khazaka GmbH)at t=0, T28 and T56.
3. Skin moisturization, measured by the Corneometer® method (Corneometer® CM 825 (Courage+Khazaka, electronic GmbH)at t=0, T28 and T56.
4. Dermatological assessment of facial skin by countin acne lesions at t=0, T28 and T56
5. Evaluation of skin inflammatory status through face digital pictures at t=0, T28 and T56.

Key secondary outcome(s)
Products tolerability, efficacy, and acceptability were evaluated in a discussion with the dermatologist at the end of the treatment.

Completion date
19/07/2019

Eligibility

Key inclusion criteria
1. Good general health
2. Both sexes, caucasian ethnicity
3. Phototype I to IV
4. Age between 18 and 50 years old
5. Acne severity from 1 to 3 according to IGA, (Investigator's Global Assessment) severity scale,
6. Subjects who have not been recently involved in any other similar study
7. Willingness to use for face care only the creams that will be consigned at the beginning of the study
8. Willingness to submit before and after pictures
9. Willingness to use during all the study period only the products to be tested
10. Willingness not to use similar products that could interfere with the product to be tested
11. Willingness to not vary the normal daily routine (i.e. lifestyle, physical activity, etc.)
12. Subject is under effective contraception (oral/not oral); not expected to be changed during the trial
13. Subject aware of the study procedures and having signed an informed consent form
14. Subjects who accept not to expose in an intensive way to UV rays during the whole study duration

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
All

Total final enrolment
80

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
2. Pregnant/breastfeeding female or who have planned pregnancy during the study period
3. Subjects under systemically pharmacological treatment
4. Subjects under locally pharmacological treatment on the skin area monitored during the test

5. Subjects with congenital or acquired immunodeficiency
6. Subjects under treatment with food supplements which could interfere with the functionality of the product under study
7. Subjects who show other skin alterations on the monitored area
8. Subjects considered as not adequate to participate in the study by the investigator
9. Subjects with known or suspected sensitization to one or more test formulation ingredients
10. Adult protected by law (under control or hospitalized in public or private institutions for reasons other than research, or incarcerated)
11. 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
17/05/2019

Date of final enrolment
24/05/2019

Locations

Countries of recruitment
Italy

Study participating centre
COMPLIFE ITALIA SRL
Via Via Mons. Angelini 21
San Martino Siccomario (PV)
Italy
27028

Sponsor information

Organisation
Complife Italia Srl

Funder(s)

Funder type
Government

Funder Name
Regione Lombardia

Alternative Name(s)
Lombardy Region, Region of Lombardy

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Italy

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. Raw data will be stored in 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 by a pdf file electronically signed. The raw data will be stored for a minimum period of 10 years in Complife servers. In the raw data tables, subjects are identified by a means of a code generated by the Complife volunteer's management software. The code is composed of a letter, 4 digits, and a letter. The access to the study raw data is allowed only to the study director and the person designated by him to elaborate the raw data. Elaboration of the raw data includes descriptive statistics (mean and standard error) and the inferential analysis (data normality and statistical test).

IPD sharing plan summary
Stored in non-publicly available repository, Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2022	18/07/2022	Yes	No
Protocol file	version 2	19/03/2019	04/11/2021	No	No