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Anti-ageing effectiveness of a food supplement

Submission date 03/01/2025	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 08/01/2025	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 06/01/2025	**Condition category** Other	[ ] 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 evaluating the efficacy of a food supplement claiming anti-ageing properties, compared with a placebo formulation.

Who can participate?
Healthy women aged between 38 and 67 years, clinically showing visible Crow's feet wrinkles (≥2 according to Skin Aging Atlas – Caucasian Type - Bazin Roland).

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 28 days after the last product intake (T84). 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 84 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 in skin appearance (reduction of skin wrinkles, increase of skin superficial and deep moisturization, improvement of skin barrier properties, increase of skin thickness and density and of skin brightness). 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/intolerance 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?
March 2023 to December 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

Study information

Scientific Title
Clinical - instrumental evaluation of the efficacy of a dietary supplement claiming anti-aging properties. A double-blind, randomized, placebo-controlled study

Acronym
Well-Ageing

Study objectives
This study aims to assess the anti-ageing efficacy of a food supplement on adult Caucasian subjects after 28 and 56 days of product intake. A follow-up visit is foreseen 28 days after the last product intake (T84).

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 05/04/2024, Independent Ethics Committee for Non-Pharmacological Clinical Investigations (Via XX Settembre 30/4, Genova, 16121, Italy; +39 (0)10 5454842; ssinf@messaggipec.it), ref: 2024/02

Primary study design
Interventional

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Subjects showing visible Crow's feet wrinkles

Interventions
Active and placebo food supplements are manufactured according to the applicable national and international rules and regulations. All ingredients included in the active and placebo formulas are approved for their use in food/food supplements.
All the active and placebo products are used as follows: 1 capsule per day, preferably far from meal, for 56 days. A follow-up visit is foreseen 28 days after the last product intake (T84).

For the entire study, all participants will apply a base cream with no cosmetics for face care two times a day (morning and evening).

Participants are randomly assigned into two groups of 33 subjects as follows:
1. 30 subjects (33 included) take the active study product
2. 30 subjects (33 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(s)
The antiaging efficacy of the tested treatment was evaluated using the following:
1. Skin profilometry (wrinkledness) measured using Primos 3D (GFMesstechnik GmbH) at baseline (T0), T28, T56, T84.
2. Dermis+ epidermis thickness and dermis density measured using high-frequency ultrasound imaging (DUB® Skin Scanner System) at T0, T56, and T84
3. Skin moisturization measured using a CORNEOMETER® (Courage+Khazaka, electronic GmbH)

at T0,T28, T56, T84
4. Skin-deep moisturization measured using the MoistureMeterEpiD (Delfin Technologies) at T0, T56, T84
5. Transepidermal water loss measured using a Tewameter 300® (Courage+Khazaka, electronic GmbH) at T0,T28, T56, T84
6. Digital pictures acquired by means of Visia®-CR (Canfield Scientific) at T0, T28, T56, T84
7. Clinical evaluation of skin wrinkledness carried out by the experimenter according to an internal clinical scale (0. No wrinkle; 1. Barely visible; 2. Visible; 3. Moderately visible; 4. Evident; 5. Very evident; 6. Marked; 7. Very marked) at T0, T28, T56, T84
8. Clinical evaluation of skin radiance carried out by the experimenter according to an internal clinical scale (1. Very dull skin; 2. Moderately dull skin; 3. Slightly dull skin; 4. Sufficiently bright skin; 5. Very bright skin), at T0, T28, T56, T84

Key secondary outcome(s)
1. Total skin antioxidant capacity measured using the FRAP assay on skin-stripping at T0 and T56
2. Evaluations of cytokines concentration (TNF-alpha cytokines) measured using an ELISA assay on skin-stripping at T0 and T56
3. Product acceptability and volunteers' perceived efficacy measured using a self-assessment questionnaire at T56
4. Product safety measured using adverse events recording throughout the study (T28 and T56)

Completion date
20/12/2024

Eligibility

Key inclusion criteria
1. Healthy Caucasian female (50%) and male (50%) subjects
2. Aged between 38 and 67 (extremes included) years old
3. Subjects showing visible Crow's feet wrinkles (≥2 according to Skin Aging Atlas – Caucasian Type - Bazin Roland)
4. Subjects with normal to dry skin
5. Subjects who have not been recently involved in any other similar study
6. Willingness to use during the study period only the product to be tested
7. Subjects certifying the truthfulness of the personal data disclosed to the investigator
8. Subjects able to understand the language used in the investigation center and the information given by the investigator
9. Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements
10. 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
11. Commitment not to change the daily routine or the lifestyle
12. Subjects have 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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
38 Years

Upper age limit
67 Years

Sex
Female

Total final enrolment
66

Key exclusion criteria
1. Those who do not fit the inclusion criteria
2. Individuals participating or planning to participate in other clinical trials
3. Persons deprived of freedom by administrative or legal decision or under guardianship
4. Individuals not able to be contacted in case of emergency
5. Persons admitted to a health or social facility
6. Individuals planning a hospitalization during the study
7. Participants who participated in a similar study without respecting an adequate washout period
8. Individuals having an acute, chronic, or progressive illness liable to interfere with the study data or considered by the investigator hazardous or incompatible with the study requirements
9. Persons with known hypersensitivity or allergy to one of the active ingredients
10. Individuals under pharmacological treatments that are considered incompatible with the study requirements by the investigator
11. Persons having a skin disease or condition liable to interfere with the study data or considered by the investigator hazardous or incompatible with the study requirements
12. Individuals that have shown allergies or sensitivity to cosmetic and/or probiotic products, drugs, patch, or medical devices
13. Women who are breastfeeding, pregnant, or not willing to take necessary precautions to avoid pregnancy during the study (for women of childbearing potential)
14. Individuals consuming food supplements containing probiotics and/or for skin care currently or within the past 4 weeks before the study

Date of first enrolment
17/09/2024

Date of final enrolment
26/09/2024

Locations

Countries of recruitment
Italy

Study participating centre
Complife Italia srl
Corso San Maurizio, 25A
Biella (BI)
Italy
13900

Study participating centre
Complife Italia srl
Via Fratelli Signorelli, 159
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20024

Sponsor information

Organisation
SynBalance srl

Funder(s)

Funder type
Industry

Funder Name
SynBalance srl

Results and Publications

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 using 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 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