SYNOPSIS – version n. 01 – 16/03/2026

"CLINICAL STUDY FOR THE EVALUATION OF THE ANTIAGEING PROPERTIES OF A FOOD SUPPLEMENT. CONTROLLED STUDY VS PLACEBO."

Complife Italia study code: H.E.HU.MP.NAA00.030.10.00_IT0008187b/25 - Version no. 01 – 16th March 2026

Title	"clinical study for the evaluation of the antiageing properties of a food supplement. Controlled study vs placebo."
Aim	The study aims to assess the efficacy of different food supplements in comparison, in improving skin conditions. In particular, the supplement's anti-aging efficacy and its overall benefits on skin health will be investigated by evaluating skin elasticity, firmness, profilometry (wrinkle depth), skin moisturization, skin radiance and skin fiber structure (dermis and epidermis). Objective and subjective assessments of product efficacy will be also assessed through self-assessment questionnaires. The study is a randomized, double-blind, placebo controlled, parallel, clinical trial*, carried out on 60 (66 enrolled**) healthy female subjects aged between 45 and 65 years old, enrolled according to specific inclusion and not inclusion criteria. The enrolled subjects will be randomly assigned to one of two arms based on a predefined randomization list, as follows: 33 will intake the active food supplement 2 (Prolastin); 33 will intake the placebo food supplement. **The study will be carried out under dermatological control in accordance with the ethical principles applicable to medical research, based on the following protocol* ***10% more subjects will be included to account for potential drop outs, for a total of 66 subjects.*
Study flow chart	The study duration is 84 days (12 weeks). Clinical visits are planned at baseline (T0) and after T28 (T28±2) and 84 days (T84±2) of products intake. Study schedule is as follows:

Study phases	**Initial visit (T0)**	**Intermediate visit (T28±2)**	**Final visit (T84±2)**
Signed Informed Consent Form and Privacy Policy	X	-	-
Subject's demographic data and medical history recording	X	-	-
Subject eligibility*	X	X	X
Randomization	X	-	-
Products distribution	X	-	-
Product counting	X	X	X
Product collection	-	-	X
Measurement of skin elasticity and firmness	X	X	X
Measurement of skin profilometry	X	X	X
Measurement of skin moisturization	X	X	X
Measurement of skin radiance	X	X	X
Image acquisition by means Visia-CR	X	X	X
Expert scoring (skin wrinkledness, skin tonicity, skin moisturization, skin radiance)	X	X	X
Image acquisition by means LC-OCT on 40 subjects	X	-	X
Dermis fiber analysis** on 80 subjects	X	-	X
Self-assessment questionnaire	-	X	X
AE and local tolerance assessment	-	X	X

**The experimenter checks at each visit the compliance of the subjects with all inclusion/exclusion criteria*
***Acquired pictures at T0 and T84 will be also delivered to Damae Medical Laboratories (Paris, France) at the end of the study, where dermal fiber analysis (density and overall anisotropy) will be performed.*

Products and dosage	**Active products:** **Food supplement 2 ingredients:** 100% Prolastin®. **Placebo product:** **Placebo food supplement ingredients:** 100% Maltodextrin. **Dosage and way of use** **Active products:** **Food supplement:** subjects will take two (n=2) capsules per day of product, in the morning, during breakfast with water. **Placebo product:** **Placebo food supplement:** subjects will take two (n=2) capsules per day of product, in the morning, during breakfast with water. Warnings: do not exceed the recommended dose. Keep out of reach of children. Supplements are not intended as a substitute for a varied diet and should be used as part of a healthy lifestyle.

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Objectives	**Primary objectives** The primary aim of the study is the evaluation of the tested product efficacy on skin aging as evaluated through the following end-points: - Skin elasticity and firmness (R0 and R2 parameters) - Skin profilometry (winkle depth and Ra parameter related to skin smoothness in the crow's feet area) - Skin moisturization - Skin radiance - Expert scoring (skin wrinkledness, skin tonicity, skin moisturization, skin radiance) **Secondary objectives** The secondary objective of this study is to evaluate the efficacy on skin fiber structure and pleasantness of the product as perceived by the subjects. Secondary end-points: - Dermal fibres analysis (density and overall anisotropy score) on 40 subjects – 20 subjects for each group - Self-evaluation questionnaire Moreover, the product tolerability will be monitored during the study by assessing the incidence and nature of Adverse Event (AE) and Serious Adverse Event (SAE).
Sample size	The study is planning to enroll a total of 66 healthy female subjects aged between 45 and 65 years old (extreme included) meeting all the inclusion/non-inclusion criteria.
Study duration	The study will provide 84 days of products intake and the evaluations will be performed at baseline (T0), after 28 (T28±2) and 84 (T84 ±2) days of supplementation.
Inclusion/Non-inclusion criteria	**Inclusion criteria** ✓ Good general health. ✓ Caucasian ethnicity. ✓ Female sex. ✓ Age between 45 and 65 years old (extremes included). ✓ Subjects with subjects with phototype II-IV (according to Fitzpatrick scale), presenting visible Crow's feet wrinkles (score between 1 and 2.5 according paragraph 8.5, table 3), moderate skin slackness (score between 1 and 2 according paragraph 8.5, table 4) and dull complexion (score between 1 and 2 according paragraph 8.5, table 2). ✓ Subjects who have not been recently involved in any other similar study (evaluation is performed case by case by the experimenter but at least 1 month must be elapsed between a previous study on food supplement). ✓ Subjects registered with health social security or health social insurance. ✓ Subjects having signed their written the Informed Consent Form (ICF) and Privacy Policy for their participation in the study. ✓ Subjects able to understand the language used in the investigation centre and the information given. ✓ Subjects able to comply with the protocol and follow protocol constraints and specific requirements. ✓ Willingness to use during all the study period only the product to be tested. ✓ Willingness not to use similar products that could interfere with the product to be tested (e.g. antiaging oral/topic products). ✓ Willingness to not vary the normal daily routine (i.e. lifestyle, physical activity, diet etc.) ✓ Subjects under effective contraception (oral/not oral) if women of childbearing potential; not expected to be changed during the trial ✓ Willingness to avoid direct sun to face during the duration of experiment ✓ Willingness to not use tanning beds or other light therapies to face for duration of experiment ✓ Willingness to no use of fillers, botox, or lasers during experiment ***Note1:*** *Subjects will not change their usual skincare routine throughout the entire study; the name and type of product (cream/serum) used in their normal daily routine will be recorded.* ***Note2:*** *information indicating whether the enrolled female subjects are postmenopausal or perimenopausal will be collected and included in the report.* **Non-Inclusion criteria** × Subjects who do not meet the inclusion criteria × Subject is taking part or planning to participate to another clinical study in the same or in another investigation centre × Subject who is deprived of freedom by administrative or legal decision or under guardianship × Subject admitted in a sanitary or social facilities × Subject who is planning an hospitalization during the study

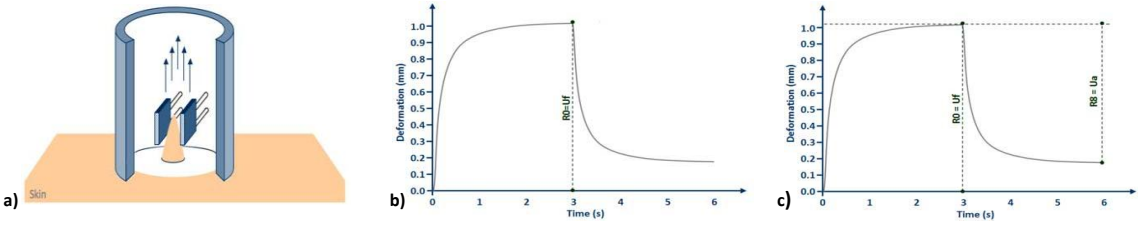
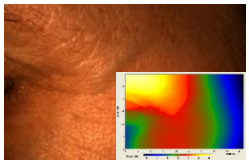
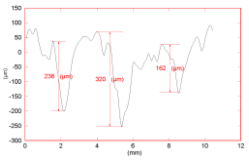
	× Subjects under treatment with food supplements which could interfere with the functionality of the product under study (e.g., supplements containing collagen peptides, hyaluronic acid, antioxidants compound or anti-inflammatory botanical extracts). × Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (if women of childbearing potential) × 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 × Subject having an acute, chronic or progressive diseases (e.g. sever 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 × Subjects under radiotherapy, chemotherapy at any time × 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 × Pharmacological treatments (topic or systemic) known to interfere with skin metabolism/physiology × Subjects under locally pharmacological/non-pharmacological treatment applied on the skin area monitored during the test × Subject with known or suspected sensitization to one or more test formulation ingredients × Subjects considered as not adequate to participate to the study by the investigator × Adult protected by law (under control or hospitalized in public or private institutions for reasons other than research, or incarcerated) × Subjects not able to communicate or cooperate with the investigator for problems related to language, mental retardation or impaired brain function. × Subjects who have used tanning beds or direct sun to the face in the previous 4 weeks × Subjects who have used fillers or botox to facial areas in the past 4 or 6 months
Treatment	The study will be randomized, parallel-group, placebo-controlled (33 will intake the active food supplement and 33 will intake the placebo food supplement). It will provide 84 days of products intake during which the evaluations will be performed at baseline (T0), after 28 (T28±2) and 84 days (T84±2).
Methods and Measurements	- **Skin elasticity/firmness (T0, T28, T84)** The measurement of skin elasticity/firmness is based on the suction method using a negative pressure mechanically deforming the skin (Cutometer® method). A Negative pressure (450 mbar) is created in the device and the skin is drawn into the aperture of the probe for 2 seconds and after a defined time (2 seconds) released again. Inside the probe, the penetration depth is determined by a non-contact optical measuring system. The optical measuring system consists of a light source and a light receptor, as well as two prisms facing each other, which project the light from transmitter to receptor. The light intensity varies due to the penetration depth of the skin. The resistance of the skin to the negative pressure and its ability to return into its original position are displayed as curves (penetration depth in mm/time) in real time during the measurement. The used device is the Cutometer® MPA 580 (Courage+Khazaka, electronic GmbH). Skin elasticity/firmness is measured in the cheek. R0, R2, parameters are measured (Fig. 1).  **Figure 1.** a) Skin elasticity/firmness measurement process. b) R0 (skin distensibility) represents the passive behaviour of the skin to force (i.e. gravity). Conceptually R0 parameter is correlated to skin firmness. c) R2 (Ua/Uf, gross elasticity or overall elasticity) represents the ability of the skin to return to its basal state. - **Wrinkles profilometry (T0, T28, T84)** Skin surface is quantitatively assessed using Primos CR-SF (Canfield Scientific). Primos CR-SF is a non- contact in vivo skin measurement device based on structured light projection (Fig. 2). In conjunction with a comprehensive 3D measurement and evaluation software, the sensor allows to evaluate skin surface properties (i.e., wrinkle depth, volume, roughness etc.). In this study the following parameter is evaluated: 1. Wrinkle depth in the crow's feet area 2. Ra parameter related to skin smoothness

Figure 2. Skin profilometry by means of Primos CR-SF analysis

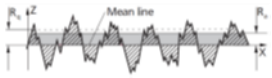


The technique. Primos CR-SF is a 3D scanner that create a point cloud (set of vertices in a three-dir system) of geometric samples on the surface of the subject. These points are then used to extrapol subject (a process called reconstruction). Like cameras, 3D-scanner has a cone-like field of view, and li only collect information about surfaces that are not obscured. While a camera collects color inform within its field of view, 3D scanners collect distance information about surfaces within its field of produced by a 3D scanner describes the distance to a surface at each point in the picture (see the ima



Calculation of wrinkle depth. It is calculated the height of wrinkles in the sampling lengths: this calc sectional picture (wrinkle depth vs. section).

Calculation of skin smoothness (Ra parameter)
For the calculation of a star roughness, intersections are arranged in a star shape by the program. T parameter occurs accordingly to the determination of the line roughness (separate for every intersection). In this study skin smoothness is calculated through the Ra parameter. Ra parameter is th of the absolute values of the roughness profile ordinates. A decrease of this parameter indicates an smoothness.



Ra is mathematically calculated as:

$$R_a = \frac{1}{l}\int_0^l |Z(x)|\, dx$$

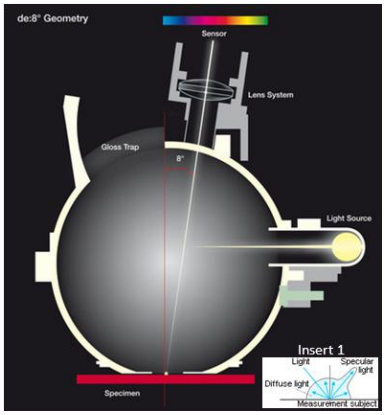
- **Skin moisturization (T0, T28, T84)**

Skin moisturization is evaluated by means of Corneometer® measurement. This measurement is based on the completely different dielectric constant of water (81) and other substances (mostly < 7). The measuring capacitor shows changes of capacitance according to the moisture content of the skin. A glass lamina separates the metallic tracks (gold) in the probe head from the skin in order to prevent current conduction in the measured area. An electric field between the tracks with alternating attraction develops. One track builds up a surplus of electrons (minus charge) the other a lack of electrons (plus charge). The scatterfield penetrates the very first layer of the skin (10-20 µm) during the measurement and the capacitance is determined.

- **Skin radiance (T0, T28, T84)**

Skin radiance (ability to reflect the light) is measured using a spectrophotometer/colorimeter CM 700D (Konica Minolta) by means of the 8° gloss value (Fig. 3).

Figure 3 Skin radiance (8° gloss value).



When light reach a surface it is reflected at the equal but opposite angle from the light source; this is called specularly reflected light. This specular component is reflected as if reflected by a mirror. The light that is not specularly reflected, but scattered in many directions, is called diffuse reflectance (insert 1). The sum of the specular reflectance plus the diffuse reflectance is called the total reflectance. For objects with shiny surfaces, the specularly reflected light is relatively strong and the diffused light is weaker. On rough surfaces with a low gloss, the specular component is weak and the diffused light is stronger. The measuring geometry d:8° features an optical device which provides diffuse illumination (Ulbricht sphere). The light (Xenon lamp) is projected into a sphere. The interior of the sphere is coated with a white highly reflecting substance (barium sulphate, ceramic, special plastic) which reflects the light manifold. A shutter, an optical element inside the sphere, prevents the directional rays from reaching the measuring sample directly. The sample is positioned at an opening of the sphere and is illuminated from all directions with a close to perfect diffuse light. Through an opening at the top of the sphere the sensor is viewing the surface being measured with an angle of 8° to the vertical. In order to prevent reflection of specular light from the sample surface, the instrument feature a gloss trap. When the trap which is arranged with an angle of -8° to the viewing opening, is open, the light which would otherwise be reflected from the interior wall of the sphere, will be eliminated and can therefore not illuminate the sample. The relation between directional and diffuse reflection allows calculating the gloss component. The measuring system including gloss is named di:8° whilst the measuring system excluding gloss is described as de:8°.

- **Expert scoring (T0, T28, T84)**

Evaluations are performed by the experimenter according to the clinical scores reported in boxes below.

1. SKIN MOISTURIZATION

Box 2. Clinical classification skin moisturization at T0, T28 and T84	Score
Dehydrated skin (very dry). Skin appears opaque with visible desquamation. It is rough to the touch, taut with irregular texture	1
Poor hydrated skin (dry). Skin appears opaque with some areas with desquamation. It is slightly rough to the touch with slightly irregular texture	2
Moderately hydrated skin. Skin appears almost luminous with some areas with desquamation. It is quite soft to the touch but not even.	3
Well hydrated skin (normal). Skin appears luminous and even. It is soft, smooth and firm to the touch.	4
Very hydrated skin (excellent hydration). Skin appears very luminous and even. It is extremely soft, velvety and smooth.	5

2. IMPROVEMENT OF SKIN LUMINOSITY

Box 3a - Clinical evaluation of skin luminosity at T0	Score	Box 3b - Clinical evaluation of the improvement of skin luminosity at T28 and T84 vs T0	Score
Strongly opaque skin	1	No variation	1
Moderately opaque skin	2	Slight improvement	2
Slightly opaque skin	3	Moderate improvement	3
Sufficiently bright skin	4	Remarkable improvement	4

3. IMPROVEMENT OF SKIN WRINKLEDNESS

Box 4a - Clinical evaluation of skin wrinkledness at T0	Score	Box 4b - Clinical evaluation of the improvement of skin wrinkledness T28 and T84 vs T0	Score
No wrinkle. No visible wrinkle; continuous skin line	0	No variation	1
Very shallow yet visible wrinkle	0.5	Slight improvement	2
Fine wrinkle. Visible winkle and slight indentation	1	Moderate improvement	3
Visible wrinkle and clear indentation	1.5	Remarkable improvement	4
Moderate wrinkle. Clearly visible wrinkle	2		
Prominent and visible wrinkle	2.5		
Deep wrinkle. Deep and furrow winkle	3		

4. SKIN TONICITY

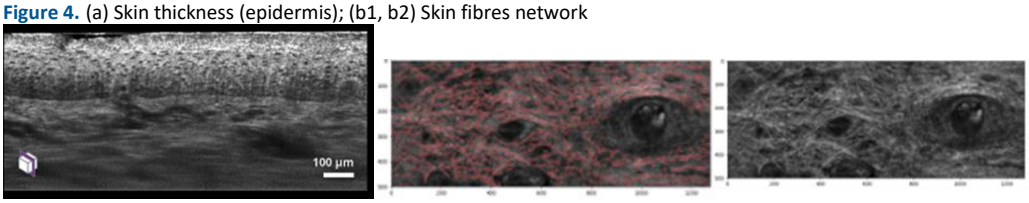
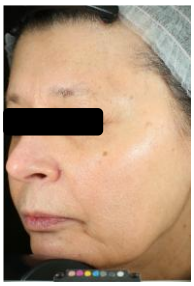
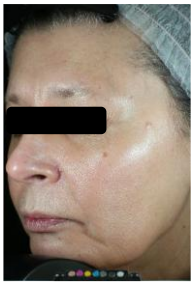
Box 5. Clinical classification skin tightness at T0, T28 and T84	Score
Not firm skin. Skin is characterized by a strong loss of tone. The skin appears completely thinned like emptied, poor dense and the tissues appear clearly relaxed.	1
Poor firm skin. Skin is characterized by an evident loss of tone. The skin appears thinned and less dense in some areas; the tissues start to relax.	2
Sufficient firm skin. Skin is characterized by a medium tone. The skin appears sufficiently full, plump and dense and the tissues appear slightly relaxed.	3
Firm skin. Skin is characterized by a good tone. The skin appears full, plump and the tissues don't appear relaxed.	4
Very firm skin. Skin is characterized by an excellent tone. The skin appears full, plump and noticeably firm.	5

- **Epidermis thickness and dermal fiber analysis – LC-OCT (T0, T28, T84) on 40 subjects – 20 subjects per group**

3D vertical stacks with isotropic cellular resolution are taken using Line field Confocal Optical Coherence Tomography (LC-OCT) technology. For each stack one horizontal image under the dermal-epidermal junction is extracted, segmented, and quantified (Fig. 4).

The epidermal and dermal fibres are automatically segmented on the horizontal images and the metrics obtained will be:

- Dermis density which reflects a number of fibres*
- Overall dermis anisotropy score calculated from the polar distribution diagram of fibre directions. The lower anisotropy score, the more isotropic, the distribution of dermal fibres, (i.e. without a preferred direction) (T0, T84)*

	Dermal fiber analysis (density and overall anisotropy) will be performed at T0 and T84 by Damae Medical Laboratories (Paris, France).* **Figure 4. (a) Skin thickness (epidermis); (b1, b2) Skin fibres network  - **Digital macrophotography (T0, T28, T84)** At each timepoint digital pictures of the face are acquired by means of Visia®-CR (Canfield Scientific). The instrument ensures a reproducible subject positioning between timepoints and acquires pictures using different light modalities. a)  b)  **Figure 5**. Examples of Visia pictures a) Standard general white lighting clinical image. b) Parallel-polarized image. *The 3 best digital pictures (standard or parallel) for each group will be included in the final report and the pictures will be delivered to the Customer in JPG format.* - **Self-assessment questionnaire (T28, T84)** A each experimental checkpoints subjects are asked to express their personal opinion on the tested products by answering to a questionnaire about products acceptability and effects.
Safety endpoints and evaluations	Tolerability of the treatment are closely followed by the study principal investigator during the course of the study. If a subject reports a reaction, the principal investigator has to decide if it is related to investigational product use. If yes, she reports it as an adverse event/serious adverse event in line with the related manifestations.