CLINICAL STUDY PROTOCOL

STUDY TITLE

CLINICAL TRIAL FOR THE ASSESSMENT OF THE EFFICACY OF
AN INGREDIENT IN SUBJECTS WITH ACUTE TELOGEN EFFLUVIUM:
A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED CLINICAL TRIAL

PROTOCOL REFERENCES
Clinical Study Protocol Number:
EC_ PIT26/0000380
Clinical Study Protocol Version and Date of issue:
Ver. 00 of 17/07/2026
Protocol:
PIT26/0000380 Ver. 01 of 15/07/2026
Study Code_Order:
H.E.HU.TE.NHL00.180.10.01_IT26/005873

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Centro di Saggio operante in BPL | Sistema di gestione qualità certificato **ISO 9001** e **ISO 13485** | Iscritto al Registro Regione Lombardia ai fini dell'autocontrollo alimentare (N. 030015309008)

GENERAL INFORMATION

SPONSOR

Name and Address:
BCF Life Sciences - Bretagne Chimie Fine 56140 Pleucadeuc – FRANCE

Authorized Signatory:
Jean-Philippe SOULARD – Human Health R&D Manager

INVESTIGATORS AND SITES

Study Setting:
Multicenter

Principal Investigator:
Dr. Enza Cestone, Specialist in dermatology

Co-Investigators:
Dr. Valentina Cortale, Efficacy Clinical Trial Supervisor

Principal Study center:
Complife Italia S.r.l. - Via Monsignor Angelini 21, San Martino Siccomario (PV) 27028 – Italy

Other Study Centers and Associated Co-Investigators:
The number of study sites and associated co-investigators will be defined, as appropriate to ensure the proper conduct of the study, during the study start-up phase and documented in a separate document, subject to review and approval by the Sponsor, the Principal Investigator, the Project Manager, and the Ethics Committee (see Annex 1 for the list of potential study centers).

MANAGEMENT

Responsible Person:
Dr. Silvia Pimazzoni, Clinical Trial Project Manager

Facility Name and address:
Complife Italia S.r.l.; office in Viale Indipendenza, 11 - 27100 Pavia (PV), Italy
Headquarters: Via Guido Rossa, 1 - 20024 Garbagnate Milanese (MI), Italy

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PROTOCOL APPROVAL

The undersigned acknowledge having read and understood the Clinical Study Protocol EC_ PIT26/0000380 Ver.oo of 17/07/2026. They hereby agree to its content and commit to conduct or oversee the study in full compliance with this Protocol, the Declaration of Helsinki, Good Clinical Practice (GCP), and applicable regulatory requirements.

AUTHORIZED SIGNATORY OF THE SPONSOR
Jean-Philippe SOULARD – Human Health R&D Manager
Date and Signature:

16th of July 2026

PRINCIPAL INVESTIGATOR
Dr. Enza Cestone, Specialist in dermatology
Date and Signature:

DOTT.SSA ENZA CESTONE
Digitally signed by Enza Cestone
Date: 2026.07.16 17:21:29 +02'00'

RESPONSIBLE FOR STUDY MANAGEMENT
Dr. Silvia Pimazzoni, Clinical Trial Project Manager
Date and Signature:

Digitally signed by Silvia Pimazzoni
Date: 2026.07.17 09:15:27 +02'00'

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PROTOCOL AMENDMENTS

All protocol amendments must be jointly approved and signed by the Sponsor, the Principal Investigator, and the Project Manager of the study.
Deviations during the study will be reviewed to determine whether they require a formal amendment or justify study termination.

AMENDMENTS HISTORY

Clinical Study Protocol Version and Date of issue:
00, 17/07/2026
Description:
First release

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SUMMARY

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1. PROTOCOL SUMMARY

The aim of this study is to evaluate the efficacy of a food supplement in subjects with acute telogen effluvium.
To reach this goal, a double-blind, randomized, placebo-controlled clinical study is planned to be performed on 176 (considering an anticipated 10% drop-out rate) healthy subjects, aged between 18 and 65 years, with acute telogen effluvium, long hair (women) or a minimum hair length by 5 cm (men), under the supervision of a board-certified Dermatologist. Subjects will be randomly assigned to receive either the active product or the placebo. Forty-four women (n = 44) will receive the active product at a dose of 300 mg/day **[Group 1]**, twenty-two men (n = 22) will receive the active product at a dose of 500 mg/day **[Group 2]**, forty-four women (n = 44) will receive the active product at a dose of 500 mg/day **[Group 3]**, forty-four women (n = 44) **[Group 4]** and twenty-two men (n = 22) **[Group 5]** will receive the placebo product for 3 months (84 days), according to the instruction for use. Specific assessments will be carried out at baseline (M0) and after 1 (M1) and 3 (M3) months of product intake. The occurrence of adverse events will be also recorded.

2. BACKGROUND AND RATIONALE

This trial follows previous clinical investigations and publications on the effects of Kera-Diet® supplementation on hair, nails and skin, including the studies by Nobile et al. (2021)[1] and Tursi et al. (2024)[2].
In the first study, a randomized, double-blind, placebo-controlled clinical trial involving women with acute telogen effluvium and brittle nail syndrome, daily supplementation with 1000 mg of Kera-Diet® combined with trace elements and vitamins for 90 days significantly improved hair density, the percentage of hairs in the anagen phase, hair and nail brightness, and nail growth compared with placebo.
The treatment also resulted in a rapid normalization of the hair pull test, suggesting a reduction in active hair shedding.
These findings supported the role of keratin-derived amino acids and associated micronutrients in improving hair and nail physiology in subjects experiencing increased hair loss and brittle nails.
Subsequently, a second randomized, double-blind, placebo-controlled clinical trial evaluated the effects of a novel keratin hydrolysate (as a sole ingredient, without any formulation) at daily doses of both 500 mg and 1000 mg in adult women showing physiological signs of skin aging.
The study demonstrated significant improvements in multiple skin parameters, including hydration, elasticity, roughness, wrinkle appearance, skin thickness and gloss, together with enhanced hair appearance.
Based on these encouraging findings, in the current protocol we aim at reducing the daily dosage of Kera-Diet®, testing both 500 mg/day and 300 mg/day, using Kera-Diet as a sole active ingredient in the finished product, targeting women and men populations.

1- Nobile V, Tursi F., Cestone E., Sergheraert R., Duperray J. The effects of the oral supplementation with a natural keratin hydrolysate (Kera-Diet®) on hair and nails : Randomized, placebo and benchmark-controlled clinical trial on healthy females. 2021, Trichol. Cosmetol. Open J. 2021.
2- Tursi F. ; Vincenzo N. ; Cestone E. ; De Ponti I. ; Lepoudère A. ; Sergheraert R. ; Soulard JP. : The Effects of an Oral Supplementation of a Natural Keratin Hydrolysate on Skin Aging: A Randomized, Double-Blind, Placebo-Controlled Clinical Study in Healthy Women. Journal of Cosmetic Dermatology, 2024; 0:1–13. https://doi.org/10.1111/jocd.16626

3. OBJECTIVES

3.1. Primary objective

The primary objective of this study is to evaluate the efficacy of the product, in particular in reducing hair shedding in female and male subjects showing acute telogen effluvium.

Primary end-points:

- Analysis performed by Phototricogram:
  - Hair diameter (µm)
  - Anagen hair (%)
  - Telogen hair (%)
  - Total number of hairs in anagen phase (THA)
  - Total number of hairs protected against shedding (HPF)
  - Hair density (number/cm$_2$)

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- Analysis performed by Pull test:
  - Number of extracted hairs
- Analysis performed by Wash test:
  - Number of hair sheds during washing
- Hair shedding visual scoring (only women with long hair):
  - Self-assessment of Hair Shedding on the day before each follow-up hair-washing day using the Sinclair Hair Shedding Scale
- Analysis performed by Dynamometer (C610M Auto Tensile Tester, Labthink):
  - Hair elongation (hair elasticity) expressed as ratio of the final stretched length to the initial hair length
- Analysis performed by digital force gauge:
  - Assessment of the hair anchorage force to scalp: the force needed to pluck hair from the scalp will be measured with a digital force gauge.
- Analysis performed by Dermatoscope:
  - Scalp appearance
- Analysis performed by DermaLab Hydration Pin Probe:
  - Scalp hydration
- Analysis performed by millimeter-graduated ruler:
  - Hair growth rate expressed as the ratio between the hair length and the time

3.2. Secondary objectives

The secondary objective of this study is to evaluate the efficacy of the product in improving hair conditions and investigate the satisfaction and efficacy of the product perceived by the subjects.
Secondary end-points:
- Digital pictures acquisition of the hair to assess the efficacy of the test product. The pictures of three subjects (per group) showing the best effect will be included.
- Images acquired with Scanning electronic microscopy (SEM). The pictures of three subjects (per group) showing the best effect will be included.
- Self-evaluation questionnaire at each follow-up visit (questions with four possible answers: completely agree / agree / disagree / completely disagree – questions with two possible answers: Yes / No)

4. STUDY DESIGN

The study will be double-blind, randomized and placebo-controlled: forty-four women (n = 44) will receive the active product at a dose of 300 mg/day **[Group 1]**, twenty-two men (n = 22) will receive the active product at a dose of 500 mg/day **[Group 2]**, forty-four women (n = 44) will receive the active product at a dose of 500 mg/day **[Group 3]**, forty-four women (n = 44) **[Group 4]** and twenty-two men (n = 22) **[Group 5]** will receive the placebo. Subjects will take the assigned food supplement for 3 months according to the directions for use.

4.1. Randomization

A restricted randomization list will be generated by an independent technician using the appropriate algorithm ("Wei's urn") of the PASS 11 software (PASS, LLC. Kaysville, UT, USA) and stored in a secure location. The Principal Investigator or designated personnel will dispense the products according to the generated randomization list.

4.2. Blinding

The study will be double-blind, meaning that subjects, Principal Investigator and collaborators will be kept masked to products assignment. The products will be supplied in the same packaging with no obvious differences between the products (see Annex 2).

5. INVESTIGATIONAL PRODUCTS

5.1. Composition

The composition of the study products is reported below.

Active Kera-Diet®, mix of amino acids
It is a keratin hydrolysate per se filled with the active ingredient Kera-Diet and rice starch (as excipient).

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COMPOSITION: Sodium chloride, Serine, Proline, Glutamic acid, Tyrosine, Glycine, Cystine, Valine, Leucine, Aspartic acid, Arginine, Alanine, Phenylalanine, Threonine, Isoleucine, Lysine, Histidine, Methionine.

Allergens:
None

Placebo
excipient Maltodextrin

Allergens:
None

The food supplements comply with current national and international legislation. The Sponsor is responsible for providing a statement confirming this compliance

5.2. Dosage and direction of use
2 capsules in the morning

5.3. Supply and storage
The products will be supplied by the Sponsor.
The delivery address is: Complife S.r.l., Via Monsignor Angelini, 21, 27028, S. Martino Siccomario (PV), Italy.
The contact person is Sabrina Martinazzo (@: segreteriapavia@complifegroup.com; T: +39 0382 25504).
Products will be stored at room temperature protected from direct light, heat and source of water safe place with restricted access.

6. STUDY POPULATION

6.1. Sample size
The study will be performed on 176 (160 + 16, considering a 10% drop-out) subjects.

6.1. Subjects' enrolment
Subjects are enrolled according to specific inclusion and exclusion criteria listed in the sections below.
All inclusion and exclusion criteria are checked by the Principal Investigator or designated personnel. The Principal Investigator maintains a record of all subjects who are enrolled and who are considered screen-failed (i.e., subject who signs the informed consent form and is not enrolled) and for each subject, the primary reason for not enrolling is recorded. Subjects enrolled are identified by a unique code that remains personal and cannot be associated to another subject during the study.

6.1.1. Inclusion criteria
1. Healthy female and male subjects
2. Subjects with skin types I to IV all included with no specific distribution across phototype groups.
3. Subjects aged between 18 and 65 years (extremes included)
4. Subjects with acute telogen effluvium, long hair (women) or a minimum hair length by 5 cm (men) at the recruitment
5. Subjects registered with the national public health system in the country where the study is conducted
6. Subjects certifying the truthfulness of the personal data disclosed to the Principal Investigator or designated personnel
7. Subjects able to understand the language used in the investigation centre and the information given by the Principal Investigator or designated personnel
8. Subjects able to respect the instructions given by the Principal Investigator or designated personnel as well as able to respect the study constraints and specific requirements
9. Subjects who commit not to change their daily routine or lifestyle during the study**
10. Subjects on stable pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) for at least one month without any changes expected or planned during the study
11. Subjects informed about the test procedures who have signed a consent form and privacy agreement

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**Subjects are asked not to change their usual dietary style, and hair hygiene and styling products (such as shampoo, conditioner, hair gel, hairspray, etc.) throughout the study

6.1.2. Exclusion criteria

1. Subjects who do not meet the inclusion criteria
2. Subjects with kinky hair
3. Subjects with any acute, chronic, or progressive disease or condition that may interfere with the study data or that the Principal Investigator considers dangerous to the subject or incompatible with the requirements of the study
4. Subjects participating or planning to participate in other clinical trials
5. Subjects who participated in a similar study without respecting an adequate washout period (at least one month)
6. Subjects that have food intolerances or food allergies to ingredients of the study product
7. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the Principal Investigator
8. Subjects who are currently using food supplement(s) and/or products with the same activity as the study product, or who haven't observed an adequate washout period (at least one month)
9. Subjects admitted to a health or social facility
10. Subjects planning a hospitalization during the study
11. Subjects not able to be contacted in case of emergency
12. Subjects deprived of freedom by administrative or legal decision or under guardianship
13. Subjects who have or have had a history of alcohol or drug addiction
14. Subjects with eating disorders (i.e. bulimia, psychogenic eating disorders, etc.)
15. Subjects breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential).

6.2. Subject withdrawal and discontinuation

In compliance with the Declaration of Helsinki, subjects have the right to withdraw from the study at any time and for any reason. In all cases, the Principal Investigator or designated personnel will attempt to contact the subject as soon as possible for a final assessment to: i) document the subject's decision on the informed consent form, ii) record the reason(s) for withdrawal on the data collection sheet, iii) evaluate the subject's clinical condition, if relevant iv) provide appropriate therapeutic measures if necessary (e.g., management of Adverse Events or concomitant conditions), v) collect any investigational product provided to the subject.

If a subject misses a scheduled visit, the Principal Investigator or designated personnel will attempt to contact the subject by phone on two separate occasions. If the subject cannot be reached after these attempts, they will be considered lost to follow-up. These contact attempts and their outcomes will be documented in the source document.

The Principal Investigator may decide to withdraw a participant from the study if the subject no longer meets the eligibility criteria, fails to comply with the protocol, or is considered unsuitable to continue participation.

This may occur, for example, in the event of illness, pregnancy, or the occurrence of an Adverse Event (AE) or Serious Adverse Event (SAE), particularly if the subject's health may be at risk or if concomitant treatments required are incompatible with continuation in the study. In such cases, the Sponsor will be notified immediately, and a detailed report explaining the reason for withdrawal will be forwarded as soon as possible. Any early termination related to an AE or SAE will be monitored until its resolution.

The Sponsor has the right to exclude any subject from the trial for major protocol violations, administrative reasons, or other justifiable reasons.

However, a high dropout rate may compromise or invalidate the interpretability of the study. Therefore, premature exits without valid reasons should be minimized and carefully documented in the case report form, the final report, and, if applicable, in the AE form. Each premature exit will be categorized as follows: i) violation of inclusion and exclusion criteria, ii) occurrence of an AE, iii) occurrence of an SAE, iv) withdrawal of consent, v) lost to follow-up, vi) non-adherence to the protocol, vii) other reason (to be clearly specified).

Subjects who withdraw, are lost to follow-up, or drop out will not be replaced.

Further details regarding safety reporting and management are provided in Paragraph 12.

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6.3. Subject full participation

Study completion is achieved when a subject has completed all treatment and has attended all scheduled visits.

7. ETHICAL CONSIDERATIONS

7.1. Risk and benefit

The food supplement administered in this study is in compliance with current food legislation and is composed of ingredients with a well-established history of safe use in humans.

No adverse effects are expected under the indication of use. However, as with any food product, the possibility of individual reactions cannot be completely excluded. If applicable, information regarding the presence of any substances that may cause hypersensitivity will be provided prior to participation.

The potential benefits associated with the use of the product are related to the improvement of hair conditions, in particular the reduction of hair shedding.

7.2. Compliance with the Declaration of Helsinki

The study will be conducted in accordance with the ethical principles for medical research (Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and amendments).

7.3. Informed Consent

During the recruitment phase, the Principal Investigator or designated personnel will explain to each subject the nature, purpose, potential benefits, and possible risks of participation in the study. The investigator must ensure that the subject has understood all relevant aspects of the study. Sufficient time will be provided to allow questions to be asked and answered.

After this discussion, subjects will be asked to carefully read and sign the study information sheet and informed consent form, and the privacy agreement pursuant to art. 13 of EU Regulation 2016/679.

The informed consent form, approved by the Sponsor, will be prepared in two versions: a version in English and a version in the local language, written in terms readily understandable to the subject. Only the version in the local language will be presented to and signed by study participants.

The informed consent form, approved by the Sponsor, will contain all required elements in language that is readily understandable to the subject. Each original consent form, personally signed and dated by both the subject and the investigator conducting the consent discussion, will be retained by the investigator. A copy will be provided to the subject. Subjects will be informed that they have the right to withdraw their consent.

The consent form may need to be revised during the study, either because important new information has become available that may be relevant to the safety of the subjects, or because of protocol amendments. It is the investigator's responsibility to ensure that the amended form is signed by all subjects who are subsequently entered into the study, as well as by those who are already in it. This will be documented in the same way as previously described

7.4. Confidentiality and Data Protection

All information, data, and results of the study are strictly confidential, and all individuals with access to such data are informed of this obligation.

In accordance with applicable data protection legislation (EU Regulation 2016/679), personal data collected during the study, including special categories of data such as date of birth, sex, race, and health-related information, will be processed confidentially and exclusively for research purposes related to this study. If the results arising from the clinical study should be published or disseminated in scientific journals or conferences, this is done in a manner that preserves confidentiality. For this purpose, relevant subject data may be forwarded to the Sponsor or its partners abroad. In each case, subject data will be pseudonymised and identified only by a code number and initials. The Principal Investigator will be responsible for maintaining the list of codes that links each subject's number with their identity.

In all cases, nominative information shall not be transmitted to the Sponsor. If a subject's name appears on a document required by the Sponsor (e.g., photographs), the name will be permanently blacked out by the site personnel, leaving only the initials visible and annotating the subject number for identification.

The data will remain strictly confidential and will not be made public. However, at any time during or after the study, health authorities may be granted direct access to the records to verify the accuracy of the collected information. In such cases, subject identity may be disclosed. All individuals granted access to these records are bound by professional secrecy.

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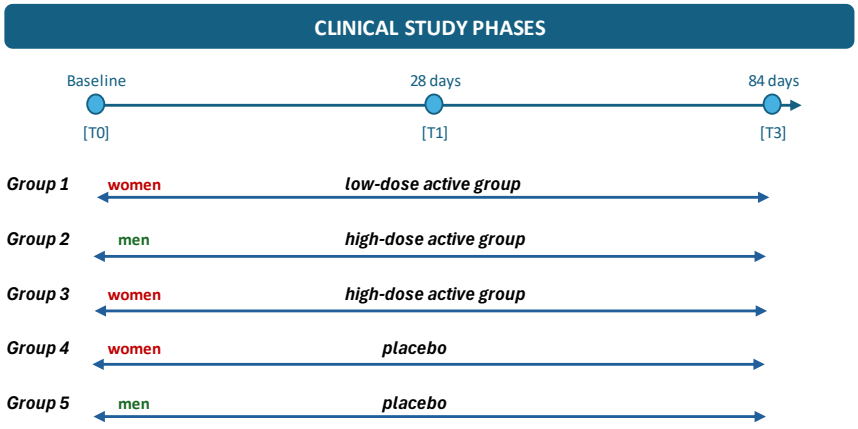
8. STUDY SCHEDULE AND PROCEDURES

The study will last 84 ± 2 days. Clinical visits are planned at T0 (Initial visit), T1 (follow-up visit, after 28 ± 2 days of treatment) and at T3 (final visit, after 84 ± 2 days of treatment).

8.1 Timeline diagram

A schematic flow diagram is provided below:



8.2. Summary of study visits and procedures

The following table summarizes the planned visits and procedures:

Procedures	T0	T1	T3
Signature of informed consent and privacy statement of screened subjects	X	-	-
Verification of subject eligibility	X	X	X
Collection of subjects' demographic data and variables relevant to eligibility assessment	X	-	-
Randomization to treatment	X	-	-
Distribution of products	X	-	-
Completion of food diaries	X	X	X
Execution of Phototrichogram	X*	X*	X*
Execution of Pull test	X	X	X
Execution of Wash test	X	X	X
Execution of Scalp analysis: scalp appearance	X	X	X
Execution of Scalp analysis: scalp hydration	X	X	X
Measurements of Hair elongation (hair elasticity)	X	X	X
Measurements of Hair growth rate (hair length)	X	X	X
Assessment of Hair Shedding	X	X	X
Assessment of the Hair anchorage force to scalp	X	X	X
Digital photographs acquisition	X	X	X
Execution of Scanning Electronic Microscopy (SEM)	X	X	X
Completion of the self-assessment questionnaire by subjects	-	X	X
Collection and counting of products	-	X	X

*A follow-up visit is scheduled 48 hours after the visit for the assessment of phototrichogram parameters (for details see paragraph 9.1.)

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8.3. Baseline visit (T0)

Subjects to be enrolled will be screened in the volunteer database by appropriate personnel (authorized by the investigator, in accordance with applicable data protection legislation) and invited to participate in the study.
At the first visit, the Principal Investigator or designated personnel will assess whether each participant meets all inclusion and exclusion criteria and collect the subject's demographic data together with the variables relevant to eligibility assessment. Subjects will be informed of the study procedure and will be asked to sign an informed consent form and an authorization for the personal data treatment.
Procedures related to the phototrichogram, pull test and wash test will be performed. Then, also the following parameters will be measured/assessed: scalp appearance, scalp hydration, hair elongation, hair growth rate, hair shedding, hair anchorage force to scalp. Moreover, digital pictures and images with Scanning Electronic Microscopy (SEM) will be acquired. During the baseline visit, subjects will receive the daily food diary.
According to the previously defined randomization list, forty-four women (n = 44) will receive the active product at a dose of 300 mg/day, twenty-two men (n = 22) will receive the active product at a dose of 500 mg/day, forty-four women (n = 44) will receive the active product at a dose of 500 mg/day, forty-four women (n = 44) and twenty-two men (n = 22) will receive the placebo. Subjects will be advised to bring back the unused products and the daily food diary at the next visit.
Subjects will be instructed to use the product in accordance with the usage instructions of the assigned product for 84 consecutive days.
The Principal Investigator or designated personnel will set the date of the follow-up visit.

8.4. Follow-up visit (T1): after 28 ± 2 days)

After 1 month (28 ± 2 days) of product intake subjects will be visited by the Principal Investigator or designated personnel who will assess whether each participant still meets all inclusion and exclusion criteria.
The participants will return the completed food diaries.
Procedures related to the phototrichogram, pull test and wash test will be performed. Then, also the following parameters will be measured/assessed: scalp appearance, scalp hydration, hair elongation, hair growth rate, hair shedding, hair anchorage force to scalp. Moreover, digital pictures and images with Scanning Electronic Microscopy (SEM) will be acquired and the recruited subjects will complete the self-assessment questionnaire.
To assess the compliance, unused product samples will be collected and counted. Subjects will be advised to bring back any unused products and the daily food diary at the next visit.
The Principal Investigator or designated personnel will set the date of the final visit.

8.5. Final visit (T3): after 84 ± 2 days)

After 3 months (84 ± 2 days) of product intake subjects will be visited by the Principal Investigator or designated personnel who will assess whether each participant still meets all inclusion and exclusion criteria.
The participants will return the completed food diaries.
Procedures related to the phototrichogram, pull test and wash test will be performed. Then, also the following parameters will be measured/assessed: scalp appearance, scalp hydration, hair elongation, hair growth rate, hair shedding, hair anchorage force to scalp. Moreover, digital pictures and images with Scanning Electronic Microscopy (SEM) will be acquired and the recruited subjects will complete the self-assessment questionnaire.
To assess the compliance, unused product samples will be collected and counted.

NOTES:

The tolerability of the product will be monitored through the reporting of adverse events throughout the entire duration of the study (see Paragraph 12).

9. TREATMENT COMPLIANCE

The Principal Investigator and designated personnel will keep a record of products given to subjects and unused products received by subjects during the visits.
Any returned product will be destroyed according to current internal procedures.

Compliance will be calculated as follows:

$$\text{Compliace to treatment} = \frac{\text{number of product taken}}{\text{number of product to intake}} \text{x}100$$

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Subjects will be defined as compliant if they use 80 –120% of the treatment regimen over the 84-day period.

10. ENDPOINTS

10.1. Analysis performed by Phototricogram

The procedure consists of the following steps:
1. Clipping: A scalp area located approximately two finger widths away from the parting line on the parietal-occipital region is clipped using a trimmer. A template (Ø 1.8 cm) is used to standardize the area.
2. Hair removal: The clipped hairs are removed with adhesive tape.
3. Imaging: A dermatoscopic photograph of the clipped area is taken 48 hours after hair clipping. The following hair cycle related parameters are measured using the TrichoScan® software:

- Hair diameter (µm)
- Anagen hair (%)
- Telogen hair (%)
- Total number of hairs in anagen phase (THA)
- Total number of hairs protected against shedding (HPF)
- Hair density (number/cm_2)

10.2. Analysis performed by Pull Test

A gentle traction is exerted on a cluster of hair (approximately 60 hairs) on at least three different areas of the scalp, and the number of extracted hairs is counted.

10.3. Analysis performed by Wash Test

Hair sheds during washing will be collected and counted.

10.4. Hair shedding visual scoring (only women with long hair)

Hair shedding will be self-assessed by subjects with long hair on the day before each follow-up hair-washing day using the Sinclair Hair Shedding Scale.

10.5. Analysis performed by Dynamometer

Hair elongation (hair elasticity) will be evaluated on individual hair fibers (n = 10) using a dynamometer under controlled temperature and humidity conditions. Hair elasticity is defined as the maximum elongation attained before breakage and is expressed as the ratio of the final stretched length to the initial hair length.

10.6. Analysis performed by digital force gauge

The assessment of the hair anchorage force to scalp is related to the force needed to pluck hair (n = 10) from the scalp, measured with a digital force gauge.

10.7. Analysis performed by Dermatoscope

This analysis is related to the evaluation of scalp appearance by the investigator

10.8. Analysis performed by DermaLab Hydration Pin Probe

The instrument quantifies the hydration level of skin by measuring its conductivity, which correlates with water content in the superficial layers. The measuring probe contains an array of 8 pins and is designed to facilitate scalp hydration measurements and to minimize water accumulation under the electrodes.

10.9. Analysis performed by millimeter-graduated ruler

Hair growth rate will be measured as the ratio between the hair length and the time. Hair length will be measured with a millimeter-graduated ruler by determining the distance from the proximal root area to the distal end of the hair shaft. Hair length will be measured on 5 hairs in the same scalp area.

10.10. Self-assessment questionnaire

Subjects are asked to reply to a self-assessment questionnaire to assess the efficacy perceived and the satisfaction of using the product. Responses are provided spontaneously, without external influence. The possible answers will be completely agree / agree / disagree / completely disagree or Yes / No (See Annex 3).

11. SUPPORT MATERIAL

11.1. Digital pictures

Digital pictures of hair will be acquired to assess the efficacy of the test product. The pictures of three subjects (per group) showing the best effect will be included

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11.2. Scanning Electronic Microscopy (SEM) images

Images with Scanning electronic microscopy (SEM) will be acquired. The pictures of three subjects (per group) showing the best effect will be included.

12. SAFETY ASSESSMENT

The tolerability of the product will be closely monitored by the study Principal Investigator during the study. Subjects will have access to the investigator via a contact phone number provided with the study information sheet in case of intolerance reactions. If a subject reports an event, the Principal Investigator will determine whether it is related to the product. If so, the event will be recorded as an adverse reaction. Any unexpected side effects related to the product will be reported to the Sponsor. At the investigator's discretion, the subject may be withdrawn from the study, in which case the side effect will be monitored until it is resolved.

12.1. Causality assessment

There are five levels of causality that can be used to determine whether the event is related to the product.

- Very likely

Clinical signs suggest a link with the product. The reaction follows a clear temporal sequence in relation to the time of product intake and rechallenge is positive.

- Likely

Clinical signs suggest a link with the product; the reaction follows a definite reasonable temporal sequence from the time of the product intake and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or clinical signs suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product intake and rechallenge is positive. Or, clinical signs only partially suggest or do not suggest a link with the product, the reaction follows a definite reasonable temporal sequence from the time of the product intake and rechallenge is positive.

- Not clearly attributable

Clinical signs suggest a link with the product; the reaction follows a definite reasonable temporal sequence from the time of the product intake and rechallenge is negative. Or clinical signs suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product intake and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or clinical signs only partially suggest or do not suggest a link with the product; the reaction follows a definite reasonable temporal sequence from the time of the product intake and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or clinical signs only partially suggest or do not suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product intake and rechallenge is positive.

- Unlikely

Clinical signs suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product intake and rechallenge is negative. Or clinical signs only partially suggest or do not suggest a link with the product; the time sequence between use of the product and occurrence of the symptoms is compatible; and rechallenge is negative. Or clinical signs only partially suggest or do not suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product intake and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or clinical signs only partially suggest or do not suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product intake and rechallenge is negative.

- Excluded

Causality can only be excluded if another aetiology has been medically validated or if the time sequence between exposure and the occurrence of signs is incompatible. In case of adverse events, subjects can also contact the Principal Investigator or designated personnel if necessary. If required, they would be assessed by the specialist who would perform the clinical assessment and decide the appropriate measures to take (i.e. medical treatment, withdrawal …).

12.2. Recording and evaluation of adverse reactions

For each sign, intensity, location, duration (hours, minutes), and frequency are recorded. Moreover, the investigator collects all discomfort or reactions reported by the subjects. Each time a sign (physical or functional) appears (new sign or worsened compared to the baseline evaluation i.e. evaluation on the first day of the study), a reaction is recorded. All the reactions observed by the specialist and reported by the subject are recorded. The following information is recorded: i) subject characteristics, ii) details about study product (product code or name, date of first use, way of use), iii) description of the reaction (functional and physical signs, intensity of the signs, location, date/time of onset,

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timeframe between product use and onset of the reaction, date/time of end or duration (hours, minutes), frequency, diagnosis/nature of the reaction), iv) significant medical history , v) concomitant events: cutaneous diseases, medical treatments, products application, food, external factors (weather conditions), other diseases, vi) outcome and actions taken (way of use modification, temporary interruption, definitive discontinuation, medical treatment, care), and vii) relationship to the product (causality assessment). This assessment is done in conjunction with clinical expertise, and knowledge of the product (type of product, conditions of use…).

12.3. Documentation of Adverse Event and Serious Adverse Event

All Adverse Events considered likely to be related to the study product, as well as all Serious Adverse Events, will be documented in the data collection sheet and included in the report of the study. If no Adverse Events occur, the report will explicitly state that no side effects were observed during the study.

12.4. Notification to the Sponsor

Any Adverse Events occurring during the study or after the study will be reported to the Sponsor's vigilance officer by e-mail **jsoulard@bcf-lifesciences.com** with a copy to the project manager, using the appropriate notification forms. Serious Adverse Event s will be reported within 24 hours of observation, and Adverse Events related to the product will be reported as soon as possible. If pictures of the reactions are available, these will be included in the notification.

12.5. Follow-up procedures

Any Adverse Event s or serious Adverse Events related to the product will be followed up until they are resolved or stabilised. To inform the Sponsor's vigilance officer of any new information, the investigator will use the appropriate forms, which will be filled in with the results collected from the examination carried out. Reports of hospitalisation will be enclosed with the notification form.

12.6. Definitions

Adverse Event (AE): An Adverse Event is any untoward medical occurrence in a clinical investigation subject administered a test product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a test product, whether related to the test product.

Serious Adverse Event (SAE): A Serious Adverse Event is any untoward medical occurrence that: i) results in death, ii) is life-threatening, iii) requires inpatient hospitalization or prolongation of existing hospitalization, iv) results in persistent or significant disability/incapacity, or v) is a congenital anomaly/birth defect.

13. DATA HANDLING AND RECORD KEEPING

13.1. Data collection

Data will be recorded in paper and/or electronic data collection sheets. The Principal Investigator or designated personnel will be responsible for completing the data collection sheets. Paper forms will be completed in blue ballpoint pen, while electronic data capture will be performed using Microsoft® Office 365 applications.

The Principal Investigator will review the data collection sheets attesting to the accuracy and completeness of the information. Any corrections made to the data collection sheets or source documents must be performed by the Principal Investigator or designated personnel in a manner that does not obscure the original entry. For paper forms, all corrections must be dated and initialled. For electronic data capture, all modifications will be automatically tracked. Where the reason for a correction is not self-evident, an explanatory note must be provided.

The Principal Investigator remains ultimately responsible for all recorded data.

In line with Good Clinical Practice, the following definitions apply to clarify the nature and origin of recorded information:

- Source Data: all original records and certified copies of original records of clinical findings, observations, or other activities necessary for the reconstruction and evaluation of the trial. Source data are contained within source documents (i.e., original records or certified copies).
- Source Documents: original documents, data, and records, such as subject files, data collection sheets, notes, or evaluation checklists.

13.2. Quality assurance

Data entry and data quality control are performed by two different persons.

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All study-related documents (including data collection sheets, the protocol, results, the report, and other documentation) are subject to quality assurance procedures in compliance with applicable regulatory requirements. Investigating sites authorize inspections by Regulatory Authorities and audits or controls by the Sponsor, granting access to source data and study records as required.

13.3. Archiving and Retention

An original copy of all study documentation (signed protocol, Sponsor's cover letter, case report forms, raw data, administrative file including all correspondence, etc.) will be retained in the records of Complife SrL for 10 years. The archives will only be destroyed after receipt of written and signed authorization from the Sponsor. However, documents will be kept for a longer period if required by applicable regulatory requirements or by agreement with the Sponsor. The Investigator must take appropriate measures to prevent accidental or premature destruction of these documents. Archiving arrangements will be defined at site close-out. The Sponsor will inform Complife SrL in writing when the documents are no longer required to be kept.

14. STATISTIC

14.1. Study population for analysis

The analysis will be conducted on the Per Protocol population. The per-protocol (PP) population is defined as all subjects who will complete the study without any major protocol violations. Subjects will be excluded from the per-protocol population if: they miss the one or more evaluation visit; or they do not used the product properly during the study period (as reported by the subject itself).
Any drop-outs and the reason for each drop-out will be reported in the final report.

14.2. Descriptive analysis

Demographic data and baseline characteristics of the enrolled population will be summarized and reported in a Microsoft® Excel spreadsheet together with the randomization list and will be summarized using: i) mean value and/or median value; ii) standard error and/or interquartile range; iii) minimum value; iv) maximum value.
Variables will include age (years), sex, ethnicity.
Endpoint variables will be recorded in a Microsoft® Excel spreadsheet, graphically represented, and analyzed using: i) mean value and/or median value; ii) standard error and/or interquartile range; iii) minimum value; iv) maximum value; v) individual variation or percentage variation versus baseline; vi) mean and/or median variation versus baseline.
The data on the self-evaluation questionnaire will be described with the frequency percentage of subjects that give a judgment among those proposed.

14.3. Inferential statistical analysis

To assess the efficacy of the product, inferential statistical analyses will be performed on the endpoints with the exception of the self-evaluation questionnaires.
For each endpoint, appropriate parametric or non-parametric technique will be applied to compare active and placebo product and to evaluate their effect over time.
No inferential analysis by subgroup will be provided.
The significance level (α) will be set at 0,05.
Statistical analysis will be performed using NCSS 10 data analysis (Copyright © 1983-2015, NCSS, LLC.) or RStudio (Copyright © 2009-2025 Posit Software, PBC).

15. ADMINISTRATIVE ASPECTS

15.1. Publication policy

The results of the study as well as any other data disclosed or generated in the context of the study are confidential. Any publication in relation to the study shall be subject to Sponsor's prior written approval and authorization of the Principal Investigator of the study.

15.2. Contractual and financial agreements

The Principal Investigator and the Sponsor sign a clinical study agreement prior to the start of the study, outlining overall Sponsor and investigator responsibilities in relation to the study. Financial remuneration covers the cost per included subject, based on the calculated costs of performing the study assessments in accordance with the protocol, and the terms of payment are described in the contract.

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15.3. Insurance

Product liability insurance may be provided by the Sponsor.

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ANNEX 1 - List of Potential Study Sites

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- Piazzale Siena 11, 20146 – Milano (MI), Italy
- Via Fratelli Signorelli 159, 20024 – Garbagnate Milanese (MI), Italy
- Via Angelini 21, 27028 – S. Martino Siccomario (PV), Italy
- Corso San Maurizio, 25 – 13900 Biella (BI), Italy
- Via Mortara 171, 44121 – Ferrara (FE), Italy

Nutratech SRL
Via Francesco Todaro 20/22, 87036 - Rende (CS), Italy

Complife France SAS
LE QUADRILLE, 18 rue Jacqueline Auriol, 69008 – Lyon, France

Complife South Africa Pty LTD
Unit H 3, The Willows Office Park, c/o Simon Vermooten and farm Roads, The Willows – Pretoria, South Africa

Complife Iberia SLU
Calle del Capitán Arenas 3, Local 3, 08028 – Barcelona, Spain

Complife (Beijing) Testing Technology Co., Ltd
Beizhan North Street 17, Room 902, Xicheng District, 100089 – Beijing, China

Complife Romania SRL
Strada Orzari 92A, 021554 – București, Romania

LLC «CRH «Vidnovlennya»
4, Lubarska Street, Zhytomyr, 10014, Ukraine

LTD HEALTH
31/35, L. Asatiani & Zubalashvili Street, 6004 Batumi, Georgia

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ANNEX 2 - Labelling

Complife SrL will affix on each product the following labels:

Figure 1. Active women-low-dose label (300 mg/day)

	Integratore alimentare	
Utilizzare in accordo con il modo d'uso Campione solo per test	**Gruppo 1** **IT26/005873** Modo d'uso: Assumere 2 compresse al mattino	Complife Sr Via Monsignor Angelini 21, San Martino Siccomario (PV) 27028 – Italy Tel. 0382 25504
AVVERTENZE: --		

Figure 2. Active men-high-dose label (500 mg/day)

	Integratore alimentare	
Utilizzare in accordo con il modo d'uso Campione solo per test	**Gruppo 2** **IT26/005873** Modo d'uso: Assumere 2 compresse al mattino	Complife Sr Via Monsignor Angelini 21, San Martino Siccomario (PV) 27028 – Italy Tel. 0382 25504
AVVERTENZE: --		

Figure 3. Active women-high-dose label (500 mg/day)

	Integratore alimentare	
Utilizzare in accordo con il modo d'uso Campione solo per test	**Gruppo 3** **IT26/005873** Modo d'uso: Assumere 2 compresse al mattino	Complife Sr Via Monsignor Angelini 21, San Martino Siccomario (PV) 27028 – Italy Tel. 0382 25504
AVVERTENZE: --		

Figure 4. Placebo (for women)

	Integratore alimentare	
Utilizzare in accordo con il modo d'uso Campione solo per test	**Gruppo 4** **IT26/005873** Modo d'uso: Assumere 2 compresse al mattino	Complife Sr Via Monsignor Angelini 21, San Martino Siccomario (PV) 27028 – Italy Tel. 0382 25504
AVVERTENZE: --		

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Figure 5. Placebo (for men)

	Integratore alimentare	
Utilizzare in accordo con il modo d'uso Campione solo per test	**Gruppo 5** **IT26/005873** Modo d'uso: Assumere 2 compresse al mattino	Complife Sr Via Monsignor Angelini 21, San Martino Siccomario (PV) 27028 – Italy Tel. 0382 25504
AVVERTENZE: --		

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ANNEX 3 - Self-assessment questionnaire

N°	Items	Completely agree	Agree	Disagree	Completely Disagree
01	I've noticed that I'm losing less hair when I wash it.	☐	☐	☐	☐
02	I've noticed that I'm losing less hair when I comb it.	☐	☐	☐	☐
03	Overall, I notice less hair loss compared to the beginning of the treatment.	☐	☐	☐	☐
04	My hair seems stronger (more resistant).	☐	☐	☐	☐
05	My hair breaks less.	☐	☐	☐	☐
06	My hair grows visibly faster than before the treatment.	☐	☐	☐	☐
07	My hair looks visibly fuller.	☐	☐	☐	☐
08	My hair looks thicker and has more body.	☐	☐	☐	☐
09	My hair looks more voluminous than at the start of the treatment.	☐	☐	☐	☐
10	I've noticed new hair growth (especially in thinning areas).	☐	☐	☐	☐
11	Overall, my hair looks visibly healthier.	☐	☐	☐	☐
12	My hair seems brighter.	☐	☐	☐	☐
13	My hair is easily disentangled.	☐	☐	☐	☐
14	I feel more confident about my appearance.	☐	☐	☐	☐

N°	Items	Yes	No
15	Other people have noticed improvements in my hair since I started the treatment?	☐	☐

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16	Would you recommend this product to a friend?	☐	☐
17	Would you buy this product?	☐	☐

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Self-assessment questionnaire (Italian translation)

N°	Domande	Completamente d'accordo	D'accordo	In disaccordo	Completamente in disaccordo
01	Ho notato una riduzione della quantità di capelli che perdo durante il lavaggio.	☐	☐	☐	☐
02	Ho notato una riduzione della quantità di capelli che perdo quando li pettino.	☐	☐	☐	☐
03	Nel complesso percepisco una diminuzione della caduta rispetto all'inizio del trattamento.	☐	☐	☐	☐
04	I miei capelli sembrano più forti (più resistenti).	☐	☐	☐	☐
05	I miei capelli si spezzano meno.	☐	☐	☐	☐
06	I miei capelli crescono visibilmente più velocemente rispetto a prima del trattamento.	☐	☐	☐	☐
07	I miei capelli appaiono visivamente più folti.	☐	☐	☐	☐
08	I miei capelli appaiono più spessi e corposi.	☐	☐	☐	☐
09	I miei capelli appaiono più voluminosi rispetto all'inizio del trattamento	☐	☐	☐	☐
10	Ho notato la comparsa di nuovi capelli (specialmente nelle aree diradate).	☐	☐	☐	☐
11	Nel complesso, i miei capelli mi appaiono visibilmente più sani.	☐	☐	☐	☐
12	I miei capelli sembrano più luminosi.	☐	☐	☐	☐
13	I miei capelli si districano facilmente.	☐	☐	☐	☐
14	Mi sento più sicura del mio aspetto.	☐	☐	☐	☐

N°	Domande	Si	No
15	Altre persone hanno notato dei miglioramenti nei miei capelli da quando ho iniziato il trattamento?	☐	☐

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16	Consiglierebbe il prodotto ad un amico?	☐	☐
17	Comprerebbe il prodotto?	☐	☐

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