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Evaluation of the efficacy of a food supplement on subjects with acute telogen effluvium

Submission date	Recruitment status	[_] Prospectively registered
22/01/2026	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/01/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
22/01/2026	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration

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Additional identifiers

Protocol no.
H.E.HU.TE.NHL00.066.15.00_IT0005805/25

Study information

Scientific Title
Clinical instrumental evaluation of the efficacy of a food supplement on subjects with acute telogen effluvium: a double-blind, multicentric, randomized, placebo-controlled study

Acronym
KerPepSuppHair

Study objectives
The study is designed to evaluate the safety and efficacy of a food supplement in reducing hair shedding in subjects with acute telogen effluvium, as well as in improving hair radiance and hair growth rate. Additionally, the effect of the product on skin and nails will be assessed through a self-assessment questionnaire.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/10/2025, Comitato Etico Indipendente per le Indagini Cliniche Non Farmacologiche (Via XX Settembre 30/4, Genova (GE), Genova, 16121, Italy; +39 010 5454842; a.scudieri@studinonfarmacologici.it), ref: 2025/18

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment, Efficacy

Study type(s)

Health condition(s) or problem(s) studied

Healthy volunteers with acute telogen effluvium

Interventions

The active intervention is a food supplement containing hydrolyzed keratin (KerPep®), while the placebo intervention contains the same excipients without the active ingredient. Both the active and the placebo products are used as follows: one capsule per day, taken in the morning prior to food intake, with sufficient liquid (water or juice).
Half of the test subjects will be randomized to receive the test product and half of the test subjects will be randomized to receive the placebo product. A restricted randomization list will be 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 the project manager and stored in a safe place. The randomization sequence will be stratified using "Efron's biased coin" algorithm with a 1:1 allocation ratio. The allocation sequence will be concealed from the project manager in sequentially numbered, opaque, and sealed envelopes, reporting the unblinded treatment allocation (based on subject entry number in the study). Each A4 sheet reporting the unblinded treatment will be folded to render the envelope impermeable to intense light. A masked allocation sequence will be prepared for the staff delivering the intervention based on the subject entry number in the study.
Participants are asked to attend clinic visits two days before the start of the study (D-2), at the beginning of study (D0) and after 30 (D30), 32 (D32), 90 (D90) and 92 (D92) days of product use. A tolerance of ± 2 days is permitted for the D30 and D90 time point.
During the screening visit, the Principal Investigator evaluates the subject's eligibility to participate in the study, and inform the participants about the trial procedures, potential risks and expected benefits. Only those who provide written informed consent are enrolled. The trial staff and the subjects fix then the date for the first visit. During the first visit, a small area (about 1.8cm²) of the scalp is shaved (phototrichogram) and hair is dyed with a hair dye.
Participants are then asked to come back to the trial facility 2 days after (the same procedure is repeated at each checkpoint).
The participants are then supplied with the active or the placebo product based on their entry number in the study. All the measurements/assessments are carried out using minimally invasive procedures. The total duration of each visit is 30 minutes. The study duration is 3 months with an intermediate check at 1 month.

Intervention Type

Supplement

Primary outcome(s)

1. Hair shedding measured using TrichoScan® supplier for the phototricogram at baseline, after 1 and 3 months

Key secondary outcome(s))

1. Acute telogen diasgnosis measured using pull test, which is a gentle traction on a bunch of hair (about 60), grasped between the thumb, index and middle fingers, on 3 different areas of the scalp (frontal, temporal, and occipital) and the number of extracted hairs is counted at baseline, after 1 and 3 months

2. Tolerability of the product intake measured using an analysis of the incidence and nature of adverse events (AEs) at baseline, after 1 and 3 months

3. Hair radiance measured using spectrophotometer/colorimeter CM 700D by means of the 8° gloss value at baseline, after 1 and 3 months

4. Hair growth speed measured using hair length assessed on five hair clipped from the scalp during the phototrichogram procedure. The length of each hair fiber will be measured using a ruler providing millimeter-scale precision at baseline, after 1 and 3 months.

5. Satisfaction of the participants measured using a self-evaluation questionnaire at 1 and 3 months

6. Effect on skin and nails measured using a self-evaluation questionnaire at 1 and 3 months

Completion date
06/03/2026

Eligibility

Key inclusion criteria
1. Female and male healthy subjects (at least 30% male for each group)
2. Age between 18 and 60 years old (extremes included)
3. Caucasian ethnicity
4. Hair length ≥ 5 cm
5. Pull test positive for acute telogen effluvium (more than 10 hairs pulled)
6. Telogen % (phototricogram) ≥ 20%
7. Willingness to use a neutral shampoo (without any claims) during the study period
8. Subjects registered with national health service
9. Subjects certifying the truthfulness of the personal data disclosed to the Investigator
10. Subjects are able to understand the language used in the investigation centre and the information given by the investigator
11. Subjects are able to respect the instructions given by the investigator, as well as able to respect the study constraints and specific requirements
12. 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
13. Commitment not to change the daily routine or lifestyle
14. Subjects providing signed informed consent and privacy documentation

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment

0

Key exclusion criteria
1. Inflammatory skin disease or progressive skin lesion on the scalp (psoriasis, seborrheic dermatitis, severe erythema, severe excoriation, severe sunburn, etc.)
2. Subjects having a scalp lesion in relief which may be traumatized
3. Systemic treatment affecting the hair growth taken for more than 4 consecutive weeks during the last 24 weeks before inclusion visit
4. Systemic or local androgenetic alopecia treatment or product, taken or applied (Minoxidil, Aminexil, Finasteride, Dutasteride, cosmetic solution or capsules with vitamin B, zinc, caffeine…) for more than 4 consecutive weeks during the last 24 weeks before the inclusion visit
5. Any other local treatment applied on the scalp (non-steroidal anti-inflammatory, ketoconazole…) within the last 2 weeks before the inclusion visit
6. Any hair care product applied on the scalp between the last shampoo and the inclusion visit (e. g., gel, hairspray, wax, foam…)
7. Radiotherapy, chemotherapy at any time
8. Scalp surgery (hair transplants, laser) at any time
9. Subjects with acute or chronic diseases able to interfere with the outcome of the study or that are considered dangerous for the subject or incompatible with the study requirements
10. Subjects participating or planning to participate in other clinical trials
11. Subjects deprived of freedom by administrative or legal decision or under guardianship
12. Subjects not able to be contacted in case of emergency
13. Subjects admitted to a health or social facility
14.Subjects planning a hospitalization during the study
15. Subjects who participated in a similar study without respecting an adequate washout period
16.Subjects having an acute, chronic or progressive illness liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
17. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the investigator (e.g. chemotherapeutic agents, anticoagulants, antibiotics, beta blockers, Angiotensinconverting enzyme inhibitors, retinoids, psychotropic medications, etc.)
18. Subjects having a skin disease or condition liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
19. Subjects that have shown allergies or sensitivity to cosmetic products, drugs, patch or medical devices
20. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential)

Date of first enrolment
05/11/2025

Date of final enrolment
12/11/2025

Locations

Countries of recruitment
Italy

Study participating centre
Complife Italia srl
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Complife Italia srl
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Sponsor information

Organisation
HKVOR

Funder(s)

Funder type

Funder Name
HKVOR

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available