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Evaluation of the effects of a food supplement in improving acute telogen effluvium in female subjects

Submission date 14/08/2026	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 09/09/2026	**Overall study status** Ongoing	
Last Edited 28/08/2026	**Condition category** Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

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Additional identifiers

Clinical Study Protocol Number
EC_ PIT26/0000380

H.E.HU.TE.NHL00.180.10.01_IT26/005873
Study Code_Order

Study information

Scientific 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

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

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/07/2026, International Ethics and Integrity Committee (Via Per Garbagnate 61, Lainate, 20045, Italy; +39 (0)3783037302; secretariat@ieicomittee.com), ref: Rif. IC0024 A

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Efficacy

Study type(s)

Health condition(s) or problem(s) studied
Acute telogen effluvium

Interventions
The active supplement consists of a keratin hydrolysate formulation containing Kera-Diet as the active ingredient and rice starch as the excipient, while the placebo contains only maltodextrin.

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 a randomized and placebo-controlled list:
1. Forty-four women (n = 44) will receive the active product at a dose of 300 mg/day
2. Forty-four women (n = 44) will receive the active product at a dose of 500 mg/day
2. Forty-four women (n = 44) will receive the placebo

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

Participants take the assigned treatment for 3 months as follows: two capsules per day in the morning, with a glass of water.

The study will last 3 months. T1 refers to the 1-month time point, while T3 refers to the final time point (3 months).

Intervention Type
Supplement

Primary outcome(s)
1. Hair diameter (µm) measured using TrichoScan® supplier and software at baseline, T1 and T3 (a follow-up visit is scheduled 48 hours after the visit for the assessment of phototrichogram parameters)

2. Anagen hair (%) measured using TrichoScan® supplier and software at baseline, T1 and T3 (a follow-up visit is scheduled 48 hours after the visit for the assessment of phototrichogram parameters)

3. Telogen hair (%) measured using TrichoScan® supplier and software at baseline, T1 and T3 (a follow-up visit is scheduled 48 hours after the visit for the assessment of phototrichogram parameters)

4. Total number of hairs in anagen phase (THA) measured using TrichoScan® supplier and software at baseline, T1 and T3 (a follow-up visit is scheduled 48 hours after the visit for the assessment of phototrichogram parameters)

5. Total number of hairs protected against shedding (HPF) measured using TrichoScan® supplier and software at baseline, T1 and T3 (a follow-up visit is scheduled 48 hours after the visit for the assessment of phototrichogram parameters)

6. Hair density (number/cm2) measured using TrichoScan® supplier and software at baseline, T1 and T3 (a follow-up visit is scheduled 48 hours after the visit for the assessment of phototrichogram parameters)

7. Number of extracted hairs measured using the Pull test at baseline, T1 and T3

8. Number of hair sheds during washing measured using the Wash test at baseline, T1 and T3

9. Hair shedding visual scoring measured using the Sinclair Hair Shedding Scale at baseline, T1 and T3

10. Hair elongation (hair elasticity) measured using dynamometer (C610M Auto Tensile Tester, Labthink) at baseline, T1 and T3

11. Assessment of the hair anchorage force to scalp measured using digital force gauge at baseline, T1 and T3

12. Scalp appearance measured using dermatoscope at baseline, T1 and T3

13. Scalp hydration measured using DermaLab Hydration Pin Probe at baseline, T1 and T3

14. Hair growth rate (expressed as the ratio between the hair length and the time) measured using millimeter-graduated ruler at baseline, T1 and T3

Key secondary outcome(s)
1. Digital pictures measured using digital camera at baseline, T1 and T3

2. Images of hair measured using scanning electronic microscopy (SEM) at baseline, T1 and T3

3. Efficacy perceived and the pleasantness of the product measured using self-evaluation questionnaire at T1 and T3

Completion date
26/02/2027

Eligibility

Key inclusion criteria
1. Healthy female 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) 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 1 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

*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

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Subjects with kinky hair
2. 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
3. Subjects participating or planning to participate in other clinical trials
4. Subjects who participated in a similar study without respecting an adequate washout period (at least 1 month)
5. Subjects that have food intolerances or food allergies to ingredients of the study product
6. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the Principal Investigator
7. 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 1 month)
8. Subjects admitted to a health or social facility
9. Subjects planning a hospitalization during the study
10. Subjects not able to be contacted in case of emergency
11. Subjects deprived of freedom by administrative or legal decision or under guardianship
12. Subjects who have or have had a history of alcohol or drug addiction
13. Subjects with eating disorders (i.e., bulimia, psychogenic eating disorders, etc)

14. Subjects 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
17/08/2026

Date of final enrolment
13/11/2026

Locations

Countries of recruitment
China

France

Georgia

Italy

Romania

South Africa

Spain

Ukraine

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Sponsor information

Organisation
BCF Life Sciences

Funder(s)

Funder type

Funder Name
BCF Life Sciences

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			14/08/2026	No	No