

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

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

Plain English summary of protocol

Not provided at time of registration

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Additional identifiers

Clinical Study Protocol Number

EC_ PIT26/0000380

Study Code_Order

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

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 male 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

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Ethics approval(s)

Approved 29/07/2026, International Ethics and Integrity Committee (Via Per Garbagnate 61, Lainate (MI), 20045, Italy; +39 (0)3783037302; secretariat@ieicomitee.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. Twenty-two men (n = 22) will receive the active product at a dose of 500 mg/day
2. Twenty-two men (n = 22) 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.

Subjects 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 a millimeter-graduated ruler at baseline, T1 and T3

Key secondary outcome(s)

1. Digital pictures measured using a 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 a self-evaluation questionnaire at T1 and T3

Completion date

26/02/2027

Eligibility

Key inclusion criteria

1. Healthy 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 with 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 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

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Male

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 one 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)

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

Study participating centre

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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