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Placebo-controlled assessment of the efficacy of a cosmetic product in subjects with hair shedding

Submission date 09/11/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/11/2026	**Overall study status** Ongoing	
Last Edited 11/11/2026	**Condition category** Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

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Additional identifiers

Clinical Study Protocol
EC_ PIT26/0000388 Ver. 00 of 18/09/2026

Study Code Order
H.E.HU.AL.NHL00.060.01.00_IT26_005796

Study information

Scientific Title
Placebo-controlled assessment of the efficacy of a cosmetic product in subjects with hair shedding: a randomized, double-blind, placebo-controlled clinical study

Study objectives
The primary objective of this study is to evaluate the efficacy of the product, in particular in reducing hair shedding.

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 29/09/2026, International Ethics and Integrity Committee (Via Per Garbagnate 61, Lainate (MI), Lainate, 20045, Italy; +39 (0)3783037302; secretariat@ieicomittee.com), ref: Rif. IC0029 A

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Transient acute telogen effluvium with different triggering causes (i.e., stress, environmental factors, seasonal changes, sudden hormonal changes)

Interventions
The active intervention is a multi-active topical scalp serum containing peptides and pea extract.

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: half of the subjects will be supplied with the active product, while the other half with 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 use the active treatment for 84 days ± 2 days as follows: separate your hair into several sections. Apply one to two drops to your scalp, making sure not to touch the skin with the dropper. Gently massage your scalp. Apply two times per day in the morning and at night.

Clinical visits are planned at M0 (initial visit), M1 (follow-up visit, after 28 days ± 2 days of treatment), M2 (follow-up visit, after 56 ± 2 days of treatment) and M3 (final visit, after 84 ± 2 days of treatment).

Intervention Type
Other

Primary outcome(s)
1. Hair anchorage force to scalp measured using a digital force gauge at M0, M1, M2 and M3

2. 60-second hair count measured using Cleopatra 400 (Krest Combs, Leominster, Massachusetts) at M0, M1, M2 and M3

3. Total hair density, % anagen hair, % telogen hair, hair diameter, total number of hairs in anagen phase (THA) and the number of hairs protected against shedding measured using TrichoScan at M0, M1, M2 and M3

4. Hair elongation and force at break measured using a dynamometer at M0, M1, M2 and M3

5. Hair length and growth speed measured using hair length measured at M0, M1, M2 and M3

6. Hair volume and scalp appearance measured using scoring system at M0, M1, M2 and M3

Key secondary outcome(s)
1. Perceived efficacy and the pleasantness of the product measured using self-evaluation questionnaire (polytomous question with four possible answers) at M0, M1, M2 and M3

2. Digital pictures of the hair measured using pictures of three subjects (per group) showing the best effect at M0, M1, M2 and M3

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. Healthy female and male subjects
2. Subjects aged between 18 and 60 years old (extremes included)
3. Subjects must have transient acute telogen effluvium* with different triggering causes (i.e., stress, environmental factors, seasonal changes, sudden hormonal changes, including at least one subject postpartum)
4. Subjects registered with the national public health system in the country where the study is conducted
5. Subjects certifying the truthfulness of the personal data disclosed to the Principal Investigator or designated personnel
6. Subjects able to understand the language used in the investigation centre and the information given by the Principal Investigator or designated personnel
7. 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
8. Subjects who commit not to change their daily routine or lifestyle during the study**
9. 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
10. Subjects informed about the test procedures who have signed a consent form and privacy agreement

* Hair shedding of less than 6 months' duration, with rapid onset following a triggering event. In the final report for each volunteer will be specify the trigger cause or causes among those listed above.
** Subjects are asked to avoid dyeing, bleaching, perms, or hairstyles involving tension/pulling during the study.

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment

0

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
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
21/10/2026

Date of final enrolment
11/11/2026

Locations

Countries of recruitment
Georgia

Study participating centre
LTD Health
31/35, L. Asatiani & Zubalashvili Street
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Sponsor information

Organisation
Aroma-Zone

Funder(s)

Funder type

Funder Name
Aroma-Zone

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available