ISRCTN38154037 https://doi.org/10.1186/ISRCTN38154037

Clinical trial for the assessment of the efficacy of cosmetic product in improving hair conditions

Submission date
07/05/2026

Recruitment status
No longer recruiting

Registration date
05/06/2026

Overall study status
Ongoing

Last Edited
07/05/2026

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

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Additional identifiers

Clinical study protocol number
EC_ 0000200/26

Study Code_Order
H.E.HU.MP.NHL00.040.02.00_IT0001994/26

Study information

Scientific Title
Clinical trial for the assessment of the efficacy of cosmetic product in improving hair conditions: a randomized, double-blind, placebo-controlled study

Study objectives
The primary objective of this study is to evaluate the efficacy of the product in reducing hair shedding by phototricogram using TrichoScan in female and male subjects showing acute telogen effluvium, in particular, monitoring the efficacy of the tested product in modulating the anagen/telogen distribution compared to placebo. The secondary objectives of this study is to evaluate the efficacy of the product in improving hair conditions and investigate the pleasantness of the product perceived by the subjects.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/03/2026, International Ethics and Integrity Committee (Via Per Garbagnate 61, Lainate (MI), Lain, 20045, Italy; +39 3783037302; secretariat@ieicomittee.com), ref: Rif. IC0020 A

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
Transient acute telogen effluvium

Interventions
The active intervention is a multi-active topical scalp serum containing peptides, plant extracts, caffeine, niacinamide and other functional actives, whereas the placebo consists of the same vehicle formulation devoid of these active ingredients.
A restricted randomization list will be generated by an independent technician using the appropriate algorithm ("Wei'surn") 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: apply daily to dry or damp hair. Divide the hair into four sections and distribute one full dropper for each section directly onto the scalp. Gently massage until fully absorbed. Do not rinse. Clinical visits are planned at T0 (Initial visit), T2 (follow-up visit, after 56 ± 2 days of product use) and at T3 (final visit, after 84 ± 2 days of product use).

Intervention Type
Other

Primary outcome(s)
1. Improvement in hair density measured using TrichoScan® supplier and software at baseline (T0), T2 and T3

2. Improvement in anagen and telogen hair (%) measured using TrichoScan® supplier and software at baseline (T0), T2 and T3

3. Improvement in anagen/telogen ratio measured using TrichoScan® supplier and software at baseline (T0), T2 and T3

Key secondary outcome(s)
1. Efficacy perceived and the pleasantness of the product measured using self-evaluation questionnaire (polytomous question with four possible answers) at T3

Completion date
04/09/2026

Eligibility

Key inclusion criteria
1. Healthy female (60%) and male (40%) subjects
2. Subjects of Caucasian ethnicity
3. Subjects aged between 18 and 60 years (extremes included)
4. Subjects with transient acute telogen effluvium (duration less than 6 months) due to fatigue, seasonal change, deficiency of vitamins and minerals, stress, change or imbalance of normal daily routing, or emotional stress*
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
*At the recruitment
** Subjects are asked not to change their usual

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 one month)
5. Subjects that have intolerances or 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 one 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. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential)
*** Including oncological diseases, diabetes, autoimmune diseases, acute inflammatory diseases, ongoing infectious diseases, and alopecia areata
**** Including corticosteroid drugs, biological drugs, and cytostatic drugs

Date of first enrolment
30/03/2026

Date of final enrolment
08/05/2026

Locations

Countries of recruitment
Italy

Romania

Study participating centre
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Sponsor information

Organisation
SKIN FIRST COSMETICS S.R.L

Funder(s)

Funder type

Funder Name
SKIN FIRST COSMETICS S.R.L

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	version 00	13/03/2026	07/05/2026	No	No