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Evaluation of a cosmetic treatment to help reduce hair loss

Submission date
11/07/2025

Recruitment status
No longer recruiting

Registration date
18/07/2025

Overall study status
Completed

Last Edited
15/07/2025

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol
Background and study aims
Acute Telogen Effluvium (ATE) is a temporary, non-scarring condition that causes sudden hair shedding, often triggered by stress, hormonal changes, nutritional issues, or environmental factors. It usually begins 2–3 months after the trigger and resolves within six months, but can significantly affect emotional well-being. Traditional treatments for chronic hair loss may not be suitable for ATE due to side effects. This has led to growing interest in natural, safer alternatives, such as vitamins, minerals, and plant-based extracts, to promote healthy hair growth. This study investigates the efficacy of Folliflo Spray, a cosmetic leave-in conditioner, in reducing hair loss in women affected by telogen effluvium.

Who can participate?
Healthy adult women with telogen effluvium.

What does the study involve?
In this study, participants will be randomly allocated to the cosmetic spray or a dummy control spray. Each participant applies their product twice daily for 3 months. During the screening visit, the medical doctor informs the participants about the trial procedure, risks, and benefits. Only participants giving their informed consent are enrolled in the study. The study includes advanced analysis of hair loss (Phototrichogram) at baseline, after 1 month, and 3 months of treatment to assess hair density and growth. Clinical assessments of hair shedding are conducted weekly, and participants complete self-evaluations at the end. The study also monitors any adverse effects throughout the trial. All the measurements/assessments performed during the visits are carried out using minimally invasive procedures.

What are the possible benefits and risks of participating?
The potential benefits associated with the use of the product are related to a reduction of hair loss.

Risks associated with the product use are considered from low to very low, in the absence of allergy/intolerances to product ingredients; other ingredients in the product formula are commonly used in cosmetic products.

Where is the study run from?
1. Complife Italia srl, San Martino Siccomario (PV), Italy
2. Complife Italia srl, Milano (MI), Italy
3. Nutratech S.r.l., Rende (CS), Italy

When is the study starting and how long is it expected to run for?
September 2024 to March 2025

Who is funding the study?
CELL ACELL, USA

Who is the main contact?
Giulia Lucerelli, giulia.lucarelli@complifegroup.com

Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
H.E.HU.TE.NHL00.040.10.00 _IT0005807/24

Study information

Scientific Title
Assessment of the efficacy of a cosmetic product claimed to reduce hair loss

Acronym
REHAIR

Study objectives
There will be a positive effect of a cosmetic product in reducing hair loss in subjects with telogen effluvium.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/10/2024, Comitato etico indipendente per le indagini cliniche non farmacologiche (Independent Ethics Committee for Non-Pharmacological Clinical Investigations) (Via XX Settembre 30/4, Genova, 16121, Italy; +39 (0)10 5454842; ssinf@messaggipec.it), ref: 2024/14

Study design
Double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Female subject with telogen effluvium

Interventions
The product under investigation is a cosmetic spray.
Half of the recruited subjects are randomized to receive the active product, while the other half receive the placebo. A restricted randomization list is generated by the Study Director using PASS 11 software (PASS, LLC, Kaysville, UT, USA) and the appropriate randomization algorithm ("Wey's urn"). The list is securely stored. An independent technician dispenses the products according to this randomization list.
The study is conducted as a double-blind trial: subjects, investigators, and collaborators are blinded to product allocation. Both the active and placebo products are provided in identical packaging, with no distinguishable differences between them.
Subjects use the assigned treatment for 3 months as follows:
They apply five sprays of the product to the entire scalp twice daily, once in the morning and once in the evening. The application involves parting the hair and spraying directly onto the

scalp in multiple areas (midline, right side, left side, and vertex), followed by a light massage to ensure even distribution. Alternatively, subjects may spray the solution five times onto the palm of their hand and then rub it onto the same areas of the scalp.
Throughout the study period, all subjects use a neutral shampoo.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Folliflo cosmetic spray

Primary outcome(s)
1. Phototricogram analysis at baseline, and after 1 month and 3 months of treatment:
1.1. Total Hair Density (number of total hairs per cm^2)
1.2. Telogen Hair Density (number of hairs in telogen phase per cm^2)
1.3. Anagen Hair Density (number of hairs in anagen phase per cm^2)
1.4. Average thickness (µm)
2. Clinical evaluation of hair shedding on the Sinclair hair shedding scale (grade 1 to grade 6) every week from week 1 to week 12

Key secondary outcome(s))
Self-assessment questionnaire (polytomous question with four possible answers) after 3 months of treatment

Completion date
28/03/2025

Eligibility

Key inclusion criteria
1. Healthy female subjects
2. Caucasian ethnicity
3. Aged over 18 years old included
4. Subject with telogen effluvium
5. Subjects aware of the study procedures and having signed an informed consent form
6. Subjects registered with National Health Service (NHS)
7. Subjects certifying the truthfulness of the personal data disclosed to the investigator
8. Subjects able to understand the language used in the investigation centre and the information given by the investigator
9. Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements
10. 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
11. Commitment not to change the daily routine or the lifestyle
12. Subject informed about the study procedures and having signed the privacy policy.

Participant type(s)

Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
68 years

Sex
Female

Total final enrolment
40

Key exclusion criteria
1. Subjects who do not fit the inclusion criteria.
2. 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
3. Subjects participating or planning to participate in other clinical trials
4. Subjects deprived of freedom by administrative or legal decision or under guardianship
5. Subjects not able to be contacted in case of emergency
6. Subjects admitted to a health or social facility
7. Subjects planning a hospitalization during the study
8. Subjects who participated in a similar study without respecting an adequate washout period
9. Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications
10. Pharmacological treatment (topic or systemic) known to interfere with the tested product or having effects on metabolism
11. Pharmacological treatment (topic or systemic) known to interfere with the tested product or having effect on metabolism (e.g.: anticoagulants, antidepressants, drugs used to lower cholesterol levels, antiviral drugs and beta-blockers)
12. Cosmetic treatment known to interfere with the tested product (e.g.: shampoo, anti-hair loss food supplements, anti-hair loss serum)
13. 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
14. Subjects that have shown allergies or sensitivity to cosmetic products, drugs, patch or medical devices
15. 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
11/11/2024

Date of final enrolment

11/12/2024

Locations

Countries of recruitment
Italy

Study participating centre
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Sponsor information

Organisation
CELL ACELL

Funder(s)

Funder type
Industry

Funder Name
CELL ACELL

Results and Publications

Individual participant data (IPD) sharing plan
Stored in a non-publicly available repository. Published as a supplement to the results publication

IPD sharing plan summary
Stored in non-publicly available repository, Published as a supplement to the results publication