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Clinical trial for the assessment of the efficacy of a food supplement in improving hair appearance

Submission date
14/07/2026

Recruitment status
No longer recruiting

Registration date
23/07/2026

Overall study status
Completed

Last Edited
14/07/2026

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

Study code/study no.
H.E.HU.TE.NHL00.060.08.00_ IT0000145/26

Study information

Scientific Title
Randomized placebo-controlled clinical trial for the assessment of the efficacy of a food supplement in improving hair appearance

Study objectives
The study is aimed to assess the efficacy of a food supplement (tested in different concentrations) in improving hair conditions in particular improving hair strength and radiance and reducing hair breakage compared to a placebo product.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/02/2026, International Ethics and Integrity Committee (IEIC) (Via Per Garbagnate 61, Lainate, 20045, Italy; +39 (0)3783037302; secretariat@ieicomittee.com), ref: IC0013 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
Thin, brittle hair that breaks easily

Interventions

The active intervention consisted of a food supplement containing L-cystine, vitamin C, ceramides, Cotinus coggygria bark extract, zinc, folic acid, and vitamin B12. The placebo consisted of a comparable excipient matrix but did not contain the active ingredients.

A restricted randomization list was 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 study personnel dispensed the study products according to the randomization list. A total of 66 participants were randomized in a 1:1:1 ratio to one of three treatment groups (22 participants per group):
Group 1: 2 tablets per day of the active food supplement and 2 tablets per day of placebo food supplement (for a total of 4 tablets per day)
Group 2: 4 tablets per day of the active food supplement
Group 3: 4 tablets per day of the placebo food supplement

The study was conducted using a double-blind design, whereby participants, the principal investigator, and all study personnel involved in the conduct and assessment of the trial remained blinded to treatment allocation throughout the study.

Participants received the assigned treatment for 84 ± 2 days.

Intervention Type
Supplement

Primary outcome(s)
1. 60-seconds hair count measured using a standardized brushing procedure (hair combing) at baseline and after 28 days and 84 days of treatment

2. Hair elasticity (hair elongation) measured using a dynamometer (C610 Autotensile Tester, Labthink) at baseline and after 28 days and 84 days of treatment

3. Hair radiance measured using a spectrophotometer/colorimeter CM 700D (Konica Minolta) at baseline and after 28 days and 84 days of treatment

4. Overall hair appearance measured using expert scoring at 28 days and 84 days of treatment

Key secondary outcome(s)
1. Efficacy perceived and the pleasantness of the product measured using a self-evaluation questionnaire at the end of the study (84 days)

Completion date
18/06/2026

Eligibility

Key inclusion criteria
1. Good general health
2. Caucasian ethnicity
3. Female sex
4. Age between 18 and 60 (+2) years old

5. Thin, brittle hair that breaks easily
6. Agree to not to take any treatment (oral or topic) able to interfere with the hair strength during the whole study duration
7. Willingness not to dye/blench hair during the 2 weeks preceding each visit
8. Willingness not to cut hair for the entire study length
9. Registered with health social security or health social insurance
10. Signed their written Informed Consent form (ICF) and Privacy Policy for their participation in the study and a photograph authorization
11. Able to understand the language used in the investigation centre and the information given
12. Able to comply with the protocol and follow protocol constraints and specific requirements
13. Willingness to take during the entire study period only the product to be tested
14. Willingness not to use/take similar products/food supplement that could interfere with the product to be tested
15. Willingness to not vary the normal daily routine (i.e. lifestyle, physical activity, diet, etc)
16. Under effective contraception (oral/not oral) if women of childbearing potential; not expected to be changed during the trial

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
62 Years

Sex
Female

Total final enrolment
66

Key exclusion criteria
1. Do not meet the inclusion criteria
2. Taking part or planning to participate to another clinical study in the same or in another investigation centre
3. Deprived of freedom by administrative or legal decision or under guardianship
4. Admitted to a sanitary or social facilities
5. Planning a hospitalization during the study
6. Under treatment with food supplements which could interfere with the functionality of the product under study
7. Participated in another clinical study with anti-hair loss product or treatment within the last 24 weeks before the inclusion visit
8. Breastfeeding or pregnant or not willing to take necessary precautions to avoid pregnancy during the study (if women of childbearing potential)
9. Has started or changed oestrogen-progesterone contraception or hormonal treatment, within the 3 months prior to the study or foreseeing it for the duration of the study
10. Having an acute, chronic or progressive illness liable to interfere with the study data or

considered by the Investigator hazardous for the subject or incompatible with the study requirements
11. Under radiotherapy or chemotherapy at any time
12. Under locally pharmacological/non-pharmacological treatment applied on the area of interest monitored during the test
13. Eating disorders
14. Any other hair disorder or hair disease (female-pattern hair loss, any type of alopecia)
15. Excessive and/or fluctuating hair shedding for more than 6 months
16. History or clinical signs of hyperandrogenaemia
17. Any hair care product applied on the scalp between the last shampoo and the inclusion visit (e.g., gel, hairspray, wax, foam)
18. Scalp surgery (hair transplants, laser) at any time

Date of first enrolment
03/03/2026

Date of final enrolment
13/03/2026

Locations

Countries of recruitment
Italy

Spain

Study participating centre
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Sponsor information

Organisation
Bios Line S.p.A.

Funder(s)

Funder type

Funder Name
Bios Line S.p.A.

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 1	29/01/2026	14/07/2026	No	No