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Clinical study to assess the efficacy of a food supplement for hair care

Submission date
21/11/2025

Recruitment status
No longer recruiting

Registration date
24/11/2025

Overall study status
Ongoing

Last Edited
03/03/2026

Condition category
Other

[_] 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
Healthy and strong hair is an important aspect of well-being and self-confidence. However, factors such as stress, diet, aging, and oxidative stress can negatively affect hair growth and quality. EVRA S.r.L., the sponsor of this study, is interested in testing a food supplement designed to improve overall hair condition, including structure, shine, and growth. The product contains Annurtrofil, an extract obtained from the Annurca apple (Malus pumila Mill. cv Annurca), a special variety traditionally ripened on straw beds after harvest. This process increases its content of polyphenols, vitamin B2, and chlorogenic acid, which are known for their antioxidant and protective effects.

Research suggests that Annurtrofil can help protect hair and skin cells from oxidative stress, improve scalp microcirculation, and stimulate the natural production of keratin, the main structural protein of hair. Clinical studies have already shown that Annurtrofil is safe and may promote hair growth and quality when taken at a daily dose of 800 mg. The aim of this new clinical study is to confirm these beneficial effects and to test whether a lower dose (400 mg /day) is also effective and well tolerated. Testing a lower dosage could make the supplement more accessible and easier to use, while providing new scientific data to support its role in hair health. The study design will help to understand the dose–response relationship and confirm the efficacy and safety of the product in improving hair condition.

Who can participate?
Healthy women and men aged between 18 and 60 years who have mild to moderate damaged hair and hair shine ranging from luster-less to lustrous.

What does the study involve?
Participants will give their written informed consent before starting the study. Participants will then be randomly assigned to three groups:
One group taking Annurtrofil 800 mg/day
One group taking Annurtrofil 400 mg/day
One group taking a placebo (a capsule with no active ingredients)

During the study, participants will take two capsules per day. The study will last 6 months (168 days ± 2 days) and will include five visits: an initial screening, a baseline visit, and follow-up visits after 56, 112, and 168 days. During the visits, the Principal Investigator or designated personnel will verify participants' eligibility and perform several hair and scalp assessments, including: measurement of hair gloss and shine, phototrichogram analysis for hair growth, evaluation of overall scalp condition, and collection of hair samples to assess elasticity, structure, and keratin content.
At follow-up visits, participants will also be asked to complete a self-assessment questionnaire. Additionally, blood tests will be performed before starting the product and after 168 days of treatment to assess tolerability.

What are the possible benefits and risks of participating?
The possible benefits include an improvement in overall hair condition, such as better structure, shine, and growth. The food supplement tested in this study complies with current food regulations and contains ingredients that are known to be safe for human use.
No side effects are expected when used as directed. However, as with any food product, there is a small chance of individual reactions. Before taking part, participants will be informed if the product contains any substances that could cause allergies or sensitivities.

Where is the study run from?
Study sites:
Complife Italia S.r.l., Italy

When is the study starting and how long is it expected to run for?
November 2025 to September 2026

Who is funding the study?
EVRA S.r.L., Italy

Who is the main contact?
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Contact information

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Additional identifiers

Protocol serial number
H.E.HU.AL.NHL00.132.01.00_IT0005615/25

Study information

Scientific Title
Clinical instrumental evaluation of the efficacy of a food supplement for hair care: a randomized, double-blind, placebo-controlled study

Acronym
HAIRSUP

Study objectives
The primary objective of this study is to evaluate the efficacy of the product in improving hair structure, shine, and growth.
The secondary objective of this study is to evaluate the efficacy and pleasantness of the product as perceived by the subjects, improvements in overall scalp condition, and the safety of use.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/11/2025, International Ethics and Integrity Committee (Via Per Garbagnate 61, Lainate (MI), 20020, Italy; +393497592449; secretariat@ieicommittee.com), ref: IC002A

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)
Efficacy, Safety, Treatment

Health condition(s) or problem(s) studied
Healthy female and male subjects with mild to moderate damaged hair and with hair shine ranging from luster-less to lustrous

Interventions
The product under investigation is a food supplement that includes Annurca apple fruit dry extract.
Participants will be randomly assigned, in equal proportions (1:1:1), to one of three treatment groups.
One third of the subjects (Group 1) will receive the active product at the higher dose (two capsules of 400 mg each, for a total daily dose of 800 mg/day). Another third (Group 2) will receive the active product at the lower dose (one 400 mg active capsule and one placebo capsule, for a total daily dose of 400 mg/day). The remaining third (Group 3) will receive two placebo capsules per day.
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. In order to ensure a balanced allocation by sex, the randomization will be stratified so that male and female participants are equally distributed among the low-dose active group, the high-dose active group, and the placebo group. The Principal Investigator or designated personnel will dispense the products according to the generated randomization list.
The study is conducted as a double-blind trial: subjects, investigators, and collaborators are blinded to product allocation. All participants will take the assigned treatment once daily, for a total duration of 168 ± 2 days, as follows:
Group 1: subjects will take two capsules of the active product once daily, in the morning on an empty stomach.
Group 2: subjects will take one capsule of the active product and one capsule of the placebo once daily, in the morning on an empty stomach.
Group 3: subjects will take two capsules of the placebo once daily, in the morning on an empty stomach.

Intervention Type
Supplement

Primary outcome(s)
1. Hair gloss (arbitrary units) measured using a spectrophotometer/colorimeter CM 700D (Konica Minolta) (the 8° gloss parameter is measured) at baseline and 56, 112 and 168 days of treatment
2. Hair density (number/cm2) measured using a phototrichogram at baseline and 56, 112 and 168 days of treatment
3. Anagen hair density (number/cm2) measured using a phototrichogram at baseline and 56, 112 and 168 days of treatment
4. Telogen hair density (number/cm2) measured using a phototrichogram at baseline and 56, 112

and 168 days of treatment
5. Anagen hair (%) measured using a phototrichogram at baseline and 56, 112 and 168 days of treatment
6. Telogen hair (%) measured using a phototrichogram at baseline and 56, 112 and 168 days of treatment
7. Anagen/telogen ratio measured using a phototrichogram at baseline and 56, 112 and 168 days of treatment
8. Hair vellus density (number/cm2) measured using a phototrichogram at baseline and 56, 112 and 168 days of treatment
9. Terminal hair density (number/cm2) measured using a phototrichogram at baseline and 56, 112 and 168 days of treatment
10. Hair thickness (µm) measured using a phototrichogram at baseline and 56, 112 and 168 days of treatment
11. Hair elasticity (%) measured using a dynamometer (C610 Autotensile Tester, LabThink) at baseline and 56, 112 and 168 days of treatment
12. Hair shine visually evaluated by the Principal Investigator and/or designated qualified personnel using a 5-point scale at baseline and 56, 112 and 168 days of treatment
13. Hair structure visually evaluated by the Principal Investigator and/or designated qualified personnel on Scanning Electron Microscopy (SEM) images using a 12-point scale at baseline and 56, 112 and 168 days of treatment
14. Keratin content (µg/mL) measured through in vitro analysis performed on collected hair samples at baseline and 56, 112 and 168 days of treatment

Key secondary outcome(s))

1. Overall scalp condition visually evaluated by the Principal Investigator and/or designated qualified personnel by observing scalp images captured with a dermatoscope and rated using a 7-point Likert scale at baseline and 56, 112 and 168 days of treatment
2. Self-assessment using a self-evaluation questionnaire (multiple choice questions/numerical rating scale from 1 to 10) 56, 112 and 168 days after treatment
3. Complete blood count (red blood cells, leukocyte count, hemoglobin, hematocrit, platelets) measured using standard medical laboratory methods at baseline, and after 168 days of treatment
4. Lactate dehydrogenase (LDH) measured using standard medical laboratory methods at baseline, and after 168 days of treatment
5. GOT transaminase (AST) measured using standard medical laboratory methods at baseline, and after 168 days of treatment
6. GPT transaminase (ALT) measured using standard medical laboratory methods at baseline, and after 168 days of treatment
7. Alkaline phosphatase measured using standard medical laboratory methods at baseline, and after 168 days of treatment
8. Creatinine measured using standard medical laboratory methods at baseline, and after 168 days of treatment
9. Total cholesterol measured using standard medical laboratory methods at baseline, and after 168 days of treatment
10. HDL cholesterol measured using standard medical laboratory methods at baseline, and after 168 days of treatment
11. LDL cholesterol measured using standard medical laboratory methods at baseline, and after 168 days of treatment
12. Triglycerides measured using standard medical laboratory methods at baseline, and after 168 days of treatment
13. Fasting glucose measured using standard medical laboratory methods at baseline, and after

168 days of treatment
14. TSH reflex measured using standard medical laboratory methods at baseline, and after 168 days of treatment
15. Prothrombin time (PT) measured using standard medical laboratory methods at baseline, and after 168 days of treatment
16. Activated partial thromboplastin time (APTT) measured using standard medical laboratory methods at baseline, and after 168 days of treatment

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Healthy female and male subjects (50% per gender in each group)
2. Subjects of Caucasian ethnicity
3. Subjects aged between 18 and 60 years (extremes included)
4. Subjects with mild to moderate damaged hair (Total hair damage score based on exposure to risk factors <18). Hair damage is evaluated using a scoring system based on the frequency of exposure to specific damaging practices and environmental factors. Each behaviour is assigned a point value according to its frequency of occurrence . The total score is then used to classify the extent of hair damage: Less than 7: Mild damage; 7 to 18: Moderate damage; 18 or more: Severe damage.
5. Subjects with hair shine ranging from luster-less to lustrous (scores 1–3 on the 5-point Visual Shine Scale). Visual evaluation is performed by the Principal Investigator or designated qualified personnel using a 5-point scale, as follows:
1 = Luster-less (little to no shine)
2 = Somewhat luster-less (slightly lacking shine)
3 = In-between (normal shine)
4 = Somewhat lustrous (slightly shiny)
5 = Lustrous (very shiny)
6. Subjects who commit to refraining from the use of any specialized hair products or topical depilatory agents throughout the study
7. Subjects who commit to not manipulating their hair, while maintaining their usual hairstyle during the study
8. Subjects who commit to using a neutral shampoo during the 2-week washout period prior to the experimental phase and throughout the entire study
9. Subjects registered with National Health Service (NHS)
10. Subjects certifying the truthfulness of the personal data disclosed to the Principal Investigator or designated personnel
11. Subjects able to understand the language used in the investigation centre and the information given by the Principal Investigator or designated personnel
12. 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
13. Subjects who commit not to change the daily routine and lifestyle during the study
14. 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
15. Subjects informed about the test procedures who have signed a consent form and privacy agreement

Participant type(s)

Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
132

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
2. Subjects with scalp or hair diseases (e.g.: scalp psoriasis, eczema, and seborrheic dermatitis) or other causes of hair loss, including androgenetic alopecia, alopecia areata, or other clinically significant alopecia conditions
3. Subjects who are taking oral contraceptives
4. 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:
4.1. AST or ALT> 2 × unl (upper normal limit)
4.2. Hepatitis, liver cirrhosis, fatty liver requiring treatment
4.3. Serum creatinine > 2 × unl, chronic renal failure, kidney disease requiring dialysis
4.4. Hypertension
4.5. Diabetes mellitus
4.6. Known malignancy within the past 5 years
4.7. Clinically relevant psychiatric conditions
4.8. Infectious skin conditions
4.9. Autoimmune diseases
5. Subjects participating or planning to participate in other clinical trials
6. Subjects who participated in a similar study without respecting an adequate washout period (at least three month)
7. Subjects that have food intolerances or food allergies to ingredients of the study product
8. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the Principal Investigator:
8.1. Use of topical hair growth agents within the past month
8.2. Application of steroid preparations to the scalp within the past month
8.3. Use of any of the following drugs within the past month: steroids, cytostatics, vasodilators, antihypertensives, anticonvulsants, beta-receptor blockers, bronchodilators, diuretics, spironolactone, cimetidine, diazoxide, cyclosporine, ketoconazole, or other agents known to affect hair growth
8.4. Use of oral antiandrogens (e.g., dutasteride, finasteride) within the last 6 months

8.5. Use of any medication known to interfere with hair growth within the past 3 months
8.6. Use of chemotherapeutic
8.7. Use of biologic medicines
9. 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 three month)
10. Subjects admitted to a health or social facility
11. Subjects planning a hospitalization during the study
12. Subjects not able to be contacted in case of emergency
13. Subjects deprived of freedom by administrative or legal decision or under guardianship
14. Subjects who have or have had a history of alcohol or drug addiction
15. Subjects with eating disorders (i.e. bulimia, psychogenic eating disorders, etc.)
16. 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
14/11/2025

Date of final enrolment
25/02/2026

Locations

Countries of recruitment
Italy

Romania

Study participating centre
Nutratech S.r.l.
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Study participating centre
Complife Romania SRL
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Sponsor information

Organisation
EVRA S.r.L.

Funder(s)

Funder type
Not defined

Funder Name
EVRA S.r.L.

Results and Publications

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

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