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Evaluation of the efficacy of a food supplement on hair trophism and normal growth in subjects with androgenetic alopecia

Submission date	Recruitment status	[_] Prospectively registered
27/01/2026	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/01/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/03/2026	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration

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Scientific, Public

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Additional identifiers

Clinical Study Protocol
EC_0003703/2024

Study information

Scientific Title
Clinical evaluation of the efficacy of a food supplement on hair trophism and normal growth in subjects with androgenetic alopecia: a randomized, double-blind, parallel-group, placebo-controlled study

Acronym
ActrisaveSuppHair

Study objectives
The primary objective of this study is to evaluate the efficacy of the product in improving hair trophism and growth, in subjects with androgenetic alopecia. The secondary objective of this study is to evaluate the efficacy of the product in improving hair radiance, volume, thickness and structure.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/11/2025, International Ethics and Integrity Committee (Via Per Garbagnate 61, Lainate (MI), Lainate, 20045, Italy; +39 3783037302; secretariat@ieicomittee.com), ref: IC006 A

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment, Safety and Efficacy

Study type(s)

Health condition(s) or problem(s) studied
Healthy volunteers with androgenetic alopecia

Interventions
The active intervention is a blend of Oryza sativa (L.) and Opuntia cus indica (L.) extracts (Actrisave™), while the placebo intervention contains the same excipients without the active 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 randomization list generated.
The study will be double-blind, meaning that subjects, Principal Investigator and collaborators are kept masked to products assignment. Both the active and placebo will be supplied in the same packaging with no obvious differences between them.
Subjects take the assigned treatment for 6 months as follows: one capsules per day intake after breakfast with water.

Intervention Type
Supplement

Primary outcome(s)
1. Hair density (anagen and telogen) and thickness measured using TrichoScan® supplier and software at baseline and after 3, 6, and 7 months

Key secondary outcome(s))
1. Hair morphology and structure measured using Scanning Electron Microscopy (SEM) for the assessment of hair morphology based on the condition of the cuticle, while hair structure is evaluated using a clinical scoring system. Variations from baseline (T0) are assessed through the analysis of digital photographs and rated on a 7-point Likert scale: Greatly decreased (–3), Moderately decreased (–2), Slightly decreased (–1), No change (0), Slightly increased (+1), Moderately increased (+2), and Greatly increased (+3) at baseline and after 3, 6, and 7 months

2. Hair gloss measured using a spectrophotometer/colorimeter CM 700D (Konica Minolta) by the 8° gloss value at baseline and after 3, 6, and 7 months

3. Hair volume measured using a clinical scoring system, in which variation from T0 at subsequent observation time points is assessed through the analysis of digital photographs and rated on a 7-point Likert scale as follows: Greatly decreased (-3), Moderately decreased (-2), Slightly decreased (-1), No change (0), Slightly increased (+1), Moderately increased (+2), Greatly increased (+3) at baseline and after 3, 6, and 7 months

4. Hair radiance measured using a clinical scoring system, in which variation from T0 at subsequent observation time points is assessed through the analysis of digital photographs and rated on a 7-point Likert scale as follows: Greatly decreased (-3), Moderately decreased (-2), Slightly decreased (-1), No change (0), Slightly increased (+1), Moderately increased (+2), Greatly increased (+3) at baseline and after 3, 6, and 7 months

5. Hair growth measured using a clinical scoring system, in which variation from T0 at subsequent observation time points is assessed through the analysis of digital photographs and rated on a 7-point Likert scale as follows: Greatly decreased (-3), Moderately decreased (-2),

Slightly decreased (-1), No change (0), Slightly increased (+1), Moderately increased (+2), Greatly increased (+3) at baseline and after 3, 6, and 7 months

6. Inflammatory status measured using blood analysis for hs-C-Reactive Protein (hs-CRP) at baseline and after 3, 6, and 7 months.

7. Assess renal tolerability measured using blood analysis for creatinine at baseline and after 3, 6, and 7 months

8. Hepatic tolerability measured using blood analysis for: Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST) and Gamma-Glutamyl Transferase (GGT) at baseline and after 3, 6, and 7 months

9. Hematological monitoring measured using blood analysis for complete blood count (CBC): red blood cells, leukocyte count, hemoglobin, hematocrit and platelets at baseline and after 3, 6, and 7 months

10. Product acceptability measured using a self-evaluation questionnaire (multiple choice and open-ended questions) at 3, 6, and 7 months

Completion date
23/10/2026

Eligibility

Key inclusion criteria
1. Healthy female subjects
2. Subjects of Caucasian ethnicity
3. Subjects aged between 18 and 64 years (extremes included)
4. Subjects with mild to moderate androgenetic alopecia *
5. Subjects with hair that is at least 5 cm long
6. Subjects with dull and mild to moderately damaged hair
7. Subjects registered with national health service
8. Subjects certifying the truthfulness of the personal data disclosed to the Principal Investigator or designated personnel
9. Subjects able to understand the language used in the investigation centre and the information given by the Principal Investigator or designated personnel
10. 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
11. Subjects who commit not to change their daily routine or lifestyle during the study **
12. 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
13. Subjects informed about the test procedures who have signed a consent form and privacy agreement

* From I to II on Ludwig scale
** Subjects are asked not to change their usual hair hygiene and styling products (such as shampoo, conditioner, hair gel, hairspray, etc.) throughout the study

Healthy volunteers allowed

Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
64 years

Sex
Female

Total final enrolment
88

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 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 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
15/12/2025

Date of final enrolment
20/03/2026

Locations

Countries of recruitment
Italy

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Sponsor information

Organisation
BIONAP S.r.l.

Funder(s)

Funder type

Funder Name
BIONAP S.r.l.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available