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Testing a natural supplement for hair loss in men and postmenopausal women

Submission date
06/05/2025

Recruitment status
No longer recruiting

Registration date
06/05/2025

Overall study status
Completed

Last Edited
06/05/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] 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
This study focuses on a common type of hair loss called androgenetic alopecia (AGA), which affects both men and women. In postmenopausal women, it is referred to as female androgenetic alopecia (FAGA). The goal of the study is to evaluate how effective and well-tolerated a food supplement containing Serenoa repens and Cucurbita pepo (AGA Plus) is in improving hair condition in individuals with mild to moderate AGA or FAGA.

Who can participate?
The study is open to men over 18 years old and postmenopausal women. All participants must have a clinical diagnosis of mild to moderate AGA or FAGA and be eligible for treatment with AGA Plus and other medications.

What does the study involve?
Participants will be involved in the study for six months, during which they will attend three clinical visits: one at the start (baseline), one at three months (optional), and one at six months. They will take one capsule of AGA Plus daily. Dermatologists will assess their hair condition using a 7-point scale, and participants will complete a questionnaire about their experience with the supplement. Hair shedding will also be checked at the three-month visit.

What are the possible benefits and risks of participating?
Participants may experience benefits such as improved hair density and reduced hair loss, along with gaining a better understanding of non-drug treatments for hair loss. Risks are minimal but could include mild stomach discomfort or allergic reactions. The supplement is not recommended for women who could become pregnant, are pregnant, or breastfeeding, and it is not suitable for vegetarians or vegans.

Where is the study run from?
Cantabria Labs Difa Cooper (Italy)

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

Who is funding the study?
Cantabria Labs Difa Cooper (Italy)

Who is the main contact?
Dr Stefano Alfano, Medical Advisor at Cantabria Labs Difa Cooper, stefano.alfano@difacooper.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Stefano Alfano

ORCID ID
https://orcid.org/0000-0003-3070-0289

Contact details
Via Milano 160
Presso Cantabria Labs Difacooper
Caronno Pertusella
Italy
21042
+39 3802607820
stefano.alfano@difacooper.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluation of the efficacy and tolerability of a supplement based on Serenoa repens and Cucurbita pepo in men and/or postmenopausal women affected by androgenetic alopecia (AGA or FAGA): a prospective, controlled, real-life study

Study objectives

The use of a food supplement containing Serenoa repens and Cucurbita pepo improves the efficacy of treatments (Minoxidil and finasteride) for androgenic alopecia in men and post-menopausal women, if compared to the treatment alone

Ethics approval required
Ethics approval not required

Ethics approval(s)
Our study was based on a food supplement and was entirely conducted in Italy. Following current Italian legislation, clinical trials based on food supplements and cosmetics do not require formal ethical approval. Anyway, this study was performed following the Helsinki Declaration, each enrolled subject signed an informed consent, and the study received approval from an external ethical committee.

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Medical and other records

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Androgenic alopecia in men and post-menopausal women

Interventions
At the baseline patients will be randomized in one of the two groups using online tools, Group A (Minoxidil or Finasteride only), Group B (Minoxidil or Finasteride+ Food supplement). Participants will be involved in the study for six months, during which they will attend three clinical visits: one at the start (baseline), one at three months (optional), and one at six months.

Intervention Type
Supplement

Primary outcome measure
Clinical efficacy will be evaluated by the dermatologist using the GLOBAL ASSESSMENT SCORE (7-Point Score), ranging from +3 to -3: Very Much Improved (+3); Moderately Improved (+2); Slightly Improved (+1); Stable (0); Slightly Worsened (–1); Moderately Worsened (–2); Very Much Worsened (–3) at baseline and 6 months

Secondary outcome measures
1. The degree of acceptability and tolerability will be assessed through a dedicated questionnaire consisting of 2 questions, each scored from 1 to 10 at 6 months
2. After 3 months, hair shedding during the initial phase of treatment will be evaluated following the Hamilton Score (for male) and the Ludwig score (for women). For each patient a representative photo will be taken

Overall study start date
20/06/2024

Completion date
06/05/2025

Eligibility

Key inclusion criteria
1. Male subjects over 18 years of age and/or postmenopausal women
2. Diagnosis of mild to moderate androgenetic alopecia (AGA or FAGA)
3. Eligible for treatment with AGA Plus and for pharmacological treatment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Group A 85 subjects, Group B 98 subjects

Total final enrolment
183

Key exclusion criteria
1. Subjects with active acute inflammatory conditions of the scalp
2. Patients undergoing pharmacological treatment for AGA or FAGA for more than three months
3. Known allergy to any of the components of the study product
4. Subjects with clinically significant iron deficiency
5. Subjects with clinically significant thyroid dysfunction
6. Subjects with dermatological conditions affecting the scalp such as alopecia areata, seborrheic dermatitis, psoriasis, mycosis, lichenoid lesions, etc.
7. Women of childbearing age and/or pregnant women

Date of first enrolment

20/06/2024

Date of final enrolment
06/05/2025

Locations

Countries of recruitment
Italy

Study participating centre
Cantabria Labs Difa Cooper
Via Milano, 160
Caronno Pertusella
Italy
21042

Sponsor information

Organisation
Cantabria Labs Difacooper

Sponsor details
Via Milano 160
Presso Cantabria Labs Difacooper
Caronno Pertusella
Italy
21042
+39 3802607820
massimo.milani@difacooper.com

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Cantabria Labs Difa Cooper

Results and Publications

Publication and dissemination plan
Data are being analysed for a future publication in an international journal

Intention to publish date
06/05/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr. Stefano Alfano, stefano.alfano@difacooper.com

IPD sharing plan summary
Available on request