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Evaluation of the efficacy and safety of a dietary supplement on hair and skin aging in subjects with androgenic alopecia

Submission date
16/07/2025

Recruitment status
No longer recruiting

Registration date
28/08/2025

Overall study status
Completed

Last Edited
18/07/2025

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
Skin aging and androgenetic hair loss are progressive conditions. This study aims to assess the effectiveness of a food supplement (Novastyne® Glow) in improving hair and skin condition.

Who can participate?
Male and female subjects aged between 33 and 67 years old, showing androgenetic hair loss and fine lines/wrinkles and loss of skin elasticity.

What does the study involve?
Participants are asked to attend clinic visits at screening and after 28, 56 and 84 days of product intake. At each visit, participants are asked to come to the study facilities on two non-consecutive days. During the screening visit, the dermatologist informs the participants about the trial procedure, risks, and benefits. Only participants giving their informed consent are enrolled in the study. The trial staff and the subjects then fix the date for the first visit. The participants are then randomly allocated to use the NOVASTYNE® Glow food supplement or the placebo product. The acquisition of measurements/assessments (phototricogram analysis using trichoscan, assessment of hair growth, assessment of hair brightness, pull test, skin moisturization, skin elasticity, skin firmness and digital macrophotography for hair and face) is carried out using minimally invasive procedures. The total duration of each visit is 1 hour. The study duration is 84 days with an intermediate check at 28 and 56 days.

What are the possible benefits and risks of participating?
The potential benefit of participating is improved hair growth and face skin condition. All the ingredients included in the product are approved for their use in food supplements and are used at the permitted concentration. The potential risks associated with the use of the product are assumed to be mild to moderate and are not expected to pose a risk to health. Risks associated with the procedures involved in this study are judged as minor. A mild skin reddening reaction may appear after the shaving procedure. This reaction is brief and fully reverts some within a few hours until complete resolution. An allergic reaction to hair dye is a rare event.

Where is the study run from?
Complife Italia Srl (Italy)

When is the study starting and how long is it expected to run for?
April 2025 to August 2025

Who is funding the study?
Novactiva (France)

Who is the main contact?
Dr Eleonora Spartà, eleonora.sparta@complifegroup.com

Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
H.E.HU.AL.NHL00.060.07.00_IT0001064/25

Study information

Scientific Title
Clinical evaluation of the efficacy and safety of a dietary supplement on hair and skin health in male and female subjects with androgenic alopecia: a randomized, placebo-controlled clinical study

Acronym
SuppHairSkin

Study objectives
The study aims to assess the efficacy and safety of a food supplement (NOVASTYNE® Glow) on hair and skin health in subjects with androgenic hair loss. In particular, the study evaluates product effectiveness in increasing the number of hairs in the anagen phase, reducing hair shedding and follicular miniaturization (hair density) and enhancing brightness, thickness and overall vitality of hair in male and female subjects showing androgenetic hair loss. In addition, it investigates the food supplement's anti-aging efficacy and its overall efficacy on skin health by improving skin moisturization and elasticity, reducing skin wrinkling and strengthening the skin’s extracellular matrix for enhanced firmness. Moreover, the pleasantness and perceived efficacy of the product are investigated through self-assessments of the subjects.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/04/2025, 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: 2025/08

Study design
Multicentric, randomized, parallel-group, placebo-controlled study.

Primary study design
Interventional

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Androgenetic alopecia, fine lines/wrinkles and loss of skin elasticity.

Interventions
The active intervention (NOVASTYNE® Glow) is a proprietary peptido amino mineral complex, while the placebo intervention is maltodextrin. Both the active and the placebo products are used as follows: two capsules per day. Half of the test subjects will be randomized to receive the

test product, and half of the test subjects will be randomized to receive the placebo product. A restricted randomization list will be created using PASS 2011 (PASS, LLC. Kaysville, UT, USA) statistical software running on Windows (Microsoft, USA) by a biostatistician and stored in a safe place. The randomization sequence will be stratified using “Efron’s biased coin” algorithm with a 1:1 allocation ratio. The allocation sequence will be concealed from the in-site project manager in sequentially numbered, opaque, and sealed envelopes, reporting the unblinded treatment allocation (based on subject entry number in the study). The A4 sheet reporting the unblinded treatment will be folded to render the envelope impermeable to intense light. A masked allocation sequence will be prepared for the staff delivering the intervention based on the subject's entry number in the study.

Participants are asked to attend clinic visits at screening and after 28, 56 and 84 days of product intake. At each visit, participants are asked to come to the study facilities on two non-consecutive days. During the screening visit, the dermatologist informs the participants about the trial procedure, risks, and benefits. Only participants giving their informed consent are enrolled in the study. The trial staff and the subjects then fix the date for the first visit. The participants are then randomly allocated to use the NOVASTYNE® Glow food supplement or the placebo product. All measurements/assessments (phototricogram analysis using trichoscan, assessment of hair growth, assessment of hair brightness, pull test, skin moisturization, skin elasticity, skin firmness and digital macrophotography on hair and face) are carried out using minimally invasive procedures. The total duration of each visit is 1 hour.

Intervention Type
Supplement

Primary outcome(s)
Phototricogram (TrichoScan®): hair density (number of total hairs per cm²), density of telogen hair (number of hairs in telogen phase per cm²) and proportion (%), density of anagen hair (number of hairs in anagen phase per cm²) and proportion (%), number of hairs protected against falling out (HPF), Hair growth (cm), Hair brightness (gloss parameter, a.u.) and Pull test (number of hair) at T0, T28, T56 and T84 days.

Key secondary outcome(s))
Skin moisturization (a.u.), Skin elasticity (R2) (Ua/Uf), Skin firmness (R0) (Uf; mm), Skin wrinkledness in the crow’s feet area (Sv parameter - µm), Skin smoothness in the crow's-feet area (Sa parameter - µm), Total wrinkle area (mm²) and Total wrinkle length (mm) at T0, T28 and T56 days. At each checkpoint, the tolerability of the treatment is followed by the study principal investigator, and subjects are asked to score product performance on a self-assessment questionnaire.

Completion date
29/08/2025

Eligibility

Key inclusion criteria
1. Good general health
2. Caucasian ethnicity
3. Female and male sex
4. Age between 33 and 67 (extremes included) years old
5. Subject showing an andro-genetic hair loss; for women I-II degrees on Ludwig scale and for

men II/III vertex degrees on Hamilton-Norwood modified scale
6. Subjects showing fine lines/wrinkles and loss of skin elasticity
7. Subjects having a positive pull test result
8. Subjects with minimum hair length of 6/7 cm
9. Subjects who stopped any anti hair loss treatment at least 3 months prior the study
10. Subjects agreeing not to take any treatment (oral or topic) able to interfere with the hair growth, diameter or fall during the whole study duration
11. Willingness not to dye/blench hair (at roots) during all the study period
12. Willingness not to cut hair for all the study length
13. Subjects registered with health social security or health social insurance
14. Subjects having signed their written Informed Consent form (ICF) and Privacy Policy for their participation in the study and a photograph authorization
15. Subjects able to understand the language used in the investigation centre and the information given
16. Subjects able to comply with the protocol and follow protocol constraints and specific requirements
17. Willingness to take during all the study period only the product to be tested
18. Willingness not to use/take similar products/food supplement that could interfere with the product to be tested
19. Willingness to not vary the normal daily routine (i.e. lifestyle, physical activity, diet etc.)
20. Subjects under effective contraception (oral/not oral) if women of childbearing potential; not expected to be changed during the trial (for women).

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
33 years

Upper age limit
67 years

Sex
All

Total final enrolment
66

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
2. Subject is taking part or planning to participate to another clinical study in the same or in another investigation centre
3. Subject who is deprived of freedom by administrative or legal decision or under guardianship
4. Subject admitted in a sanitary or social facilities
5. Subject who is planning a hospitalization during the study

6. Subject has participated in another clinical study with anti-hair loss product or treatment within the last 24 weeks before the inclusion visit
7. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (if women of childbearing potential)
8. Subject 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
9. Subjects with any acute, chronic, or progressive disease or skin condition (e.g. sever atopic dermatitis, psoriasis) that may interfere with the study data or that the investigator considers dangerous to the subject or incompatible with the requirements of the study
10. Subjects under radiotherapy, chemotherapy at any time
11. Subjects under any locally pharmacological/non-pharmacological treatment applied on the area of interest monitored during the test
12. Subject having food disorders (i.e. bulimia, psychogenic eating disorders, etc.)
13. Subject who has any other hair disorder or hair disease (e.g. any other type of alopecia…)
14. Subject having excessive and/or fluctuating hair shedding for more than 6 months
15. History or clinical signs of hyperandrogenaemia
16. Systemic treatment affecting the hair growth taken for more than 4 consecutive weeks during the last 24 weeks before inclusion visit
17. Systemic or local androgenetic alopecia treatment or product, taken or applied (Minoxidil, Aminexil, Finasteride, Dutasteride, cosmetic solution or capsules with vitamin B, zinc, caffeine…) for more than 4 consecutive weeks during the last 24 weeks before the inclusion visit
18. Any hair care product applied on the scalp between the last shampoo and the inclusion visit (e.g. gel, hairspray, wax, foam…)
19. Scalp surgery (hair transplants, laser) at any time.
20. Subjects that have food intolerances or food allergies or allergies to ingredients of the study product.

Date of first enrolment
26/05/2025

Date of final enrolment
03/06/2025

Locations

Countries of recruitment
Italy

Study participating centre
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Study participating centre

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Sponsor information

Organisation
NOVACTIVA

Funder(s)

Funder type
Industry

Funder Name
NOVACTIVA

Results and Publications

Individual participant data (IPD) sharing plan
Raw data will be stored on Complife servers. A backup copy of the raw data will also be in a cloud-based backup server. Tables containing the raw data (output of the measurements) will also be included in the study report and shared with the study sponsor in a PDF file, electronically signed. The raw data will be stored for a minimum period of 10 years on Complife servers. In the raw data tables, subjects are identified by a means of a code generated by the Complife volunteer's management software. The code is composed of a letter, four digits, and a letter. Access to the study raw data is allowed only to the project manager and the person designated by her to elaborate on the raw data. Elaboration of the raw data includes descriptive statistics (mean and standard error) and inferential analysis (data normality and statistical test).

IPD sharing plan summary

Stored in non-publicly available repository, Not expected to be made available