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Clinical evaluation of the safety and efficacy of a nutraceutical supplement in promoting hair, skin and nail health: a randomized, double blind, placebo-controlled study

Submission date
26/09/2025

Recruitment status
No longer recruiting

Registration date
29/09/2025

Overall study status
Completed

Last Edited
29/09/2025

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
This study aims to evaluate whether a new food supplement can help reduce hair loss, improve hair density, growth and brightness, strengthen nails, and enhance skin condition (moisturisation, elasticity, firmness, and brightness).

Who can participate?
Healthy men and women between 18 and 65 years old, with seasonal hair loss, brittle nails, and dry or less elastic skin, are eligible to take part. Volunteers must have hair at least 6–7 cm long, agree not to dye or bleach their hair during the study, and commit to maintaining their usual daily routines.

What does the study involve?
Participants are randomly assigned to receive either the active supplement or a placebo. They take two gummies per day for 84 days. Clinical assessments are performed at the start of the study and after 56 and 84 days. These include tests on hair loss, hair elasticity, strength and growth, nail hardness, and skin health. At the end of the study, participants also complete a short questionnaire to assess their self-perception of the supplement's efficacy.

What are the possible benefits and risks of participating?
The potential benefits of participating include improvements in overall hair, skin, and nail condition. The risks are considered very low, although individuals with allergies or intolerances to any of the ingredients are not eligible to participate.

Where is the study run from?
The study is conducted by Nutratech S.r.l. (Italy), under the supervision of a dermatologist.

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

Who is funding the study?
Nutris We Care About You S.L. (Spain)

Who is the main contact?
Dr Luigi Gardi, studiomedicogardi@gmail.com

Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
H.E.HU.HV.NAA00.060.17.00_NT0001010/24

Study information

Scientific Title
Clinical evaluation of the efficacy of a food supplement in helping to reduce hair loss and improving hair brightness, in increasing nail hardness and in improving skin condition: a randomized, double blind, placebo-controlled study

Study objectives
To evaluate the safety and efficacy of a food supplement in reducing hair loss and enhancing overall hair health, as well as improving skin condition and nail hardness.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/10/2024, Società Scientifica Italiana per le Indagini Cliniche Non Farmacologiche (Via XX Settembre 30/4, Genova, 16121, Italy; +39 (0)10 5454842; a. scudieri@studinonfarmacologici.it), ref: 2024/11

Study design
Interventional randomized double blind placebo-controlled study

Primary study design
Interventional

Study type(s)
Prevention, Quality of life, Safety, Efficacy

Health condition(s) or problem(s) studied
Seasonal hair loss, brittle nails, and dry, poorly elastic facial skin

Interventions
The study is designed as a randomized, double-blind, placebo-controlled clinical trial. A total of 66 healthy male and female volunteers aged 18–65 years are enrolled and randomized in parallel groups, with 33 subjects assigned to the active product and 33 subjects to the placebo. Randomization was performed using a restricted randomization list (Wey’s urn algorithm) and product allocation is blinded for both investigators and participants. The intervention consists of the daily oral intake of two gummies for 84 ± 2 days. The active product is NuLush Hair®, containing botanical extracts (olive leaf, horsetail, adiantum, pumpkin seed), DL-α tocopheryl acetate, zinc citrate, biotin, and sodium selenite, while the placebo product has the same appearance but no active ingredients.

Intervention Type
Supplement

Primary outcome(s)
1. Number of hairs lost measured using Pull Test and Wash Test at baseline (T0), day 56 (T56), and day 84 (T84).
2. Hair elasticity (% elongation) measured using Tensolab 2512A dynamometer according to UNI EN ISO 5079:1998 at T0, T56, and T84.

3. Hair density (hairs/cm²) measured using phototrichogram analysis with TrichoScan® at T0 and T84.
4. Hair growth (cm) measured using hair length measurement in the target area at T84.
5. Hair brightness measured using clinical scoring scale by dermatologist assessment at T0, T56, and T84.

Key secondary outcome(s))
1. Skin moisturization measured using Corneometer® at T0, T56, and T84.
2. Skin elasticity (R2) measured using Cutometer® MPA 580 at T0, T56, and T84.
3. Skin firmness (R0) measured using Cutometer® MPA 580 at T0, T56, and T84.
4. Skin brightness measured using clinical scoring scale by dermatologist assessment at T0, T56, and T84.
5. Nail hardness measured using clinical scoring scale by dermatologist assessment at baseline (T0), day 56 (T56), and day 84 (T84).
6. Subject self-assessment of product efficacy and tolerability measured using 10-item self-assessment questionnaire at T84.
7. Incidence of adverse events (AEs) and serious adverse events (SAEs) measured using standard adverse event reporting forms throughout the 84-day study period.

Completion date
23/01/2025

Eligibility

Key inclusion criteria
1. Healthy female and male subjects (without any specific repartition).
2. Caucasian ethnicity.
3. Aged between 18 and 65 years (extremes included).
4. Subjects with seasonal hair loss.
5. Subjects with brittle nails.
6. Subjects with dry and poorly elastic facial skin.
7. Subjects with minimum hair length of 6/7 cm.
8. Uncoloured hair and willingness not to dye or bleach hair during the study.
9. Willingness not to cut hair during the study.
10. Subjects registered with National Health Service (NHS).
11. Subjects certifying the truthfulness of the personal data disclosed to the investigator.
12. Subjects able to understand the language used in the investigation center and the information given by the investigator.
13. Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements.
14. Subjects committed not to change the daily routine or the lifestyle.
15. Subjects under 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.
16. Subjects informed about the test procedures who have signed a consent form and privacy policy.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
66

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria.
2. Subjects with any acute, chronic, or progressive disease or skin condition that may interfere with the study data or that the 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 1 month).
5. Subjects that have food intolerances or food allergies or allergies to ingredients of the study product.
6. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the investigator.
7. Subjects who are currently using food supplement(s) and/or topical products with the same activity as the study product, or who haven't observed an adequate washout period since stopping use (at least 1 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 with a history of drug, alcohol and other substance abuse.
13. Subjects with alimentary/eating disorders (i.e. bulimia, psychogenic eating disorders, etc.).
14. Subjects 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
15/10/2024

Date of final enrolment
29/10/2024

Locations

Countries of recruitment

Italy

Study participating centre
Nutratech S.r.l.
Via Francesco Todaro, 20/22
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Sponsor information

Organisation
Nutris We Care About You

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Veronica Gallo (vgallo@nutris.es).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes