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Effectiveness of a food supplement on hair loss

Submission date	Recruitment status	[_] Prospectively registered
04/02/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/03/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2024	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The study aims to assess the effectiveness of two doses of a dietary supplement claiming anti hair loss properties on a multi-ethnic panel of volunteers after 28 and 84 days of oral intake.

Who can participate?
Male and female volunteers (multiethnic panel) aged from 18 to 65 years old with brittle and thin hair

What does the study involve?
Participants are asked to attend clinic visits at screening and after 28 and 84 days of food supplement intake. During the screening visit, the principal investigator will inform the participants about the study procedure, risks, and benefits. Only participants giving their informed consent are enrolled in the study. The study staff and the participants then fix the date for the first visit. The participants are then randomly allocated to use one of the two doses of the active food supplement or the placebo products for 84 days. Participants will be divided into three study groups to take either one or two capsules per day of the active food supplement or to take one capsule per day of the placebo food supplement. All the measurements and assessments are carried out using non-invasive procedures. The total duration of each visit is 30 minutes. The study duration is 84 days with one intermediate check at 28 days.

What are the possible benefits and risks of participating?
The potential benefits associated with product use are reduced hair loss and improved hair strength and brightness. Risks associated with the procedures involved in this study are judged as minor. All precautions will be taken to ensure that the risk is the lowest possible. All the measurements carried out are minimally invasive and no side effects are expected from the measurement process.

Where is the study run from?
1. Nutratech srl spin-off Università della Calabria (Italy)
2. Complife Beijing Testing Technology Co., Ltd (China)

When is the study starting and how long is it expected to run for?
November 2023 to June 2024

Who is funding the study?
ROELMI HPC Srl (Italy)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
H.E.HU.TU.NHL00.060.08.00_IT0006541/23

Study information

Scientific Title
Multi-ethnic clinical-instrumental evaluation of the efficacy of two doses of a dietary supplement claiming anti-hair loss properties. A randomized, placebo-controlled study

Acronym
M.E.-hair-loss

Study objectives
The study aims to assess the efficacy of two doses of a dietary supplement claiming anti-hair loss properties on a multi-ethnic panel after 28 and 84 days of product intake.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 10/01/2024, Independent ethics committee for non-pharmacological clinical investigations (Via XX Settembre 30/4, Genova, 16121, Italy; +39 (0)10 5454842; ssinf@messaggipec.it), ref: 2023/19

Study design
Multicentric single-blind parallel-group placebo-controlled inter- and intra-group comparison study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute telogen effluvium from less than 6 months (presenting ≥15% of telogen parameter at inclusion), with a hair length of at least 5 cm, complaining of brittle and thin hair

Interventions
The test product is manufactured according to the applicable national and international rules and regulations. All ingredients included in the product formula are approved for their use in food/food supplements.

The study foresees 84 days of product consumption. Evaluations of the parameters under study are performed at baseline (T0), after 28 (T28) and 84 days (T84) of product intake.

According to a previously defined randomization list subjects are divided into three homogenous study groups as follows:
24 subjects take the first dose of the active food supplement
24 subjects take the second dose of active food supplement
24 subjects take the placebo food supplement

Each group will include:
12 Caucasian volunteers recruited in Italy of which 6 are female and 6 are male
12 Chinese volunteers recruited in China of which 6 are female and 6 are male

For group who take first dose of active food supplement and the placebo food supplement, the study foresees the intake of one capsule per day in the morning on empty stomach, between meals, with a glass of still water for the 84 days of treatment while for group who take second dose of active food supplement, the study foresees the intake of two capsules per day in the morning on an empty stomach, between meals, with a glass of still water for the 84 days of treatment.

A restricted randomization list is created using PASS 2008 (PASS, LLC. Kaysville, UT, USA) statistical software running on Windows Server 2008 R2 Standard SP1 64-bit Edition (Microsoft, USA) by a biostatistician and stored in a safe place. The randomization sequence was stratified using “Efron’s biased coin” algorithm with a 1:1 allocation ratio. The allocation sequence was concealed from the in-site study director in sequentially numbered, opaque and sealed envelopes, reporting the unblinded treatment allocation (based on the subject entry number in the study). The A4 sheet reporting the unblinded treatment was folded to render the envelope

impermeable to intense light. A masked allocation sequence was prepared for the staff delivering the intervention based on the subject entry number in the study.

Intervention Type
Supplement

Primary outcome(s)
1. Phototrichogram (total hair density [number of total hairs per cm^2], telogen hair density [number of hairs in telogen phase per cm^2] and proportion [%], anagen hair density [number of hairs in anagen phase per cm^2] and proportion [%], hair thickness) measured using TrichoScan® at baseline (T0), 28 days (T28), T84 days (T84)
2. Hair elasticity (maximum elongation before hair breakage) in Caucasian subjects measured using a dynamometer (Tensolab 2512A, Mesdan Lab.) at baseline (T0) and at T84 days (T84)
3. Hair brightness measured using the spectrophotometer/colorimeter CM-700D (Konica-Minolta) at baseline (T0) and at T84 days (T84)
4. Digital pictures acquired using a digital camera at baseline (T0), 28 days (T28) and 84 days (T84)

Key secondary outcome(s))
1. Product safety assessed using adverse events recording throughout the study (T28 and T84)
2. Product acceptability and volunteers' perceived efficacy assessed with a self-assessment questionnaire at T84

Completion date
28/06/2024

Eligibility

Key inclusion criteria
1. Healthy female (50%) and male (50%) subjects
2. Multi-ethnic panel (50% Asian and 50% Caucasian ethnicity)
3. Aged between 18 and 65 (extremes included) years old
4. All hair types included
5. Subjects showing acute telogen effluvium from less than 6 months (due to fatigue/stress /deficient diet/post-partum/hormonal/fever, etc)
6. Subjects presenting > 15% of telogen parameter at inclusion
7. Subjects with a hair length of at least 5 cm
8. Subjects complaining of brittle and thin hair
9. Subjects who stopped any anti hair loss treatment at least 3 months prior to 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. Subjects registered with health social security or health social insurance
12. Subjects able to understand the language used in the investigation center and the information given
13. Subjects able to comply with the protocol and follow the protocol's constraints and specific requirements
14. Willingness to use the same products for hair care during all the study period
15. Willingness not to cut hair for all the study length
16. Willingness not to dye hair during the 4 weeks preceding the T0 visit and during the 4 weeks preceding the T84 visit
17. Subject is aware of the study procedures and has signed an informed consent form, a photograph authorization and privacy information form

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Subject does not meet the inclusion criteria
2. Subject is taking part or planning to participate in another clinical study in the same or in another investigation centre
3. Subject is deprived of freedom by administrative or legal decision or under guardianship
4. Subject is admitted to a sanitary or social facilities
5. Subject 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 3 months before the inclusion visit
7. Subject is breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the 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. Subject having an acute, chronic or progressive illness liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
10. Subject is in the course of a treatment or intending to have one considered by the Investigator liable to interfere with the study data or incompatible with the study requirements
11. Subject having a skin/scalp condition (psoriasis, seborrheic dermatitis, severe erythema, severe excoriation, severe sunburn, etc), liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
12. Subject having a personal history of cosmetic, drug, domestic products or food supplements allergy
13. Subject having food disorders
14. Subject who has any other hair disorder or hair disease (female pattern hair loss, any type of alopecia)
15. Subject having excessive and/or fluctuating hair shedding for more than 6 months
16. History or clinical signs of hyperandrogenemia (menstrual cycle >35 days and hirsutism and acne)
17. Systemic treatment affecting the hair growth taken for more than 4 consecutive weeks during the last 24 weeks before inclusion visit: retinoids, anti-mitotic, cytotoxic drugs other than antineoplastic, anti-androgens (spironolactone, flutamide), androgens, anti-epileptic agents,

interferon alpha
18. 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
19. Any other topical treatment applied on the scalp (non-steroidal anti-inflammatory, ketoconazole…) within the last 2 weeks before the inclusion visit
20. Any following hair care within the last 2 weeks before the inclusion visit: dandruff shampoo, antifungal shampoo, dyeing, bleaching, perm,
21. Any hair care product applied on the scalp between the last shampoo and the inclusion visit (e.g. gel, hairspray, wax, foam…),
22. Radiotherapy, chemotherapy at any time
23. Use of any other product (s) similar to the one in the study
24. Scalp surgery (hair transplants, laser) at any time

Date of first enrolment
29/01/2024

Date of final enrolment
29/03/2024

Locations

Countries of recruitment
China

Italy

Study participating centre
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Sponsor information

Organisation

ROELMI HPC Srl

Funder(s)

Funder type
Industry

Funder Name
ROELMI HPC Srl

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository on Complife/Nutratech servers. A backup copy of the raw data will be also in a cloud-based backup server. Tables containing the raw data (output of the measurements) will be also included in the study report and shared with the study sponsor in a pdf file that is 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 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's raw data is allowed only by the study director and the person designated by him 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