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Evaluation of the efficacy of a food supplement (Actrisave™) on hair loss in men

Submission date
10/11/2021

Recruitment status
No longer recruiting

Registration date
12/11/2021

Overall study status
Completed

Last Edited
12/11/2021

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Androgenetic alopecia is a common skin condition that causes hair loss. The aim of this study is to assess the effectiveness of a food supplement (Actrisave™) on androgenetic alopecia in men.

Who can participate?
Patients aged 18 to 55 years with mild-to-moderate androgenetic alopecia.

What does the study involve?
Participants are asked to attend clinic visits at screening and after 3 and 6 months of product intake; an additional visit is foreseen after 1 month from the last product intake. At each visit, participants are asked to come to the study facilities on two not 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 fix then the date for the first visit. During the first visit, a small area (about 1.8 cm^2) of the scalp is shaved and the hair is dyed with a hair dye. Participants are then asked to come back to the trial facility 2 days after (the same procedure is repeated at each checkpoint). The participants are then randomly allocated to use the Actrisave™ food supplement or the placebo (dummy) product for 6 months. All the measurements/assessments are carried out using minimally invasive procedures. The total duration of each visit is 30 minutes. The study duration is 7 months with an intermediate check at 3, 6, and 7 months (follow-up visit, 1 month after product use stops).

What are the possible benefits and risks of participating?
The potential benefit of participating is improved hair growth. 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. All the precautions will be taken to

ensure that the risk of such an eventuality would be the lowest possible. All the measurements carried out are minimally invasive and no skin side effects are expected from the measurement process.

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

When is the study starting and how long is it expected to run for?
November 2021 to August 2022

Who is funding the study?
BIONAP srl (Italy)

Who is the main contact?
Dr Vincenzo Nobile
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
H.E.HU.AL.NHL00.086.01.00_ IT0004094/21

Study information

Scientific Title
Double-blind, randomized, placebo-controlled assessment of the effect of a food supplement (Actrisave™) on hair trophism and normal growth in subjects with androgenetic alopecia

Acronym
AGActrisave

Study objectives
The trial is aimed to evaluate the efficacy of the test product at ameliorating mild-to-moderate androgenetic alopecia in adult male subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/11/2021, Comitato etico indipendente per le indagini cliniche non farmacologiche (Via XX Settembre 30/4 - 16121 Genova, Italy; +39 (0)10 5454842; ssinf@messaggipec.it), ref: 2021/08

Primary study design
Interventional

Study design
Multicentric randomized double-blind placebo-controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Androgenetic alopecia

Interventions
The active intervention (Actrisave™) is a blend of Oryza sativa (L.) and Opuntia cus indica (L.) extracts; while the placebo intervention is maltodextrin. Both the active and the placebo products are used as follows: one capsule per day intake after lunch or after dinner. 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 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 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 study director 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 entry number in the study.

Participants are asked to attend clinic visits at screening and after 3 and 6 months of product intake; an additional visit is foreseen after 1 month from the last product intake. At each visit, partcipants are asked to come to the study facilities on two not 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 fix then the date for the first visit. During the first visit, a small area (about 1.8 cm^2) of the scalp is shaved (phototrichogram) and hair is dyed with a hair dye. Participants are then asked to come back to the trial facility 2 days after (the same procedure is repeated at each checkpoint). The participants are then randomly allocated to use the Actrisave™ food supplement or the placebo (dummy) product for 6 months. All the measurements/assessments are carried out using minimally invasive procedures. The total duration of each visit is 30

minutes. The study duration is 7 months with an intermediate check at 3, 6, and 7 months (follow-up visit, 1 month after product use stops).

Intervention Type
Supplement

Primary outcome(s)
Hair loss related parameters (anagen, telogen, and the total hair number) measured using TrichoScan at baseline, and after 3, 6, and 7 months product use

Key secondary outcome(s)
Hair growth measured using a clinical score scale by the dermatologist at baseline, and after 3, 6, and 7 months product use. At each checkpoint subjects are also asked to score performance on a self-assessment questionnaire.

Completion date
31/08/2022

Eligibility

Key inclusion criteria
1. Healthy male subjects
2. Subjects aged between 18 and 55 years old inclusive
3. Subjects with all types of scalp and hair
4. Subjects registered with health social security or health social insurance
5. Subjects having signed their written Informed Consent Form (ICF) for their participation in the study and a photograph authorization
6. Subjects certifying the truth of the personal information declared to the Investigator
7. Subjects able to understand the language used in the investigation center and the information given
8. Subjects able to comply with the protocol and follow protocol’s constraints and specific requirements
9. Subjects considered a “healthy subject” by the Investigator
10. If the subject is under systemic pharmacological treatment, this should be stable for at least 1 month before the study start and do not change over the study period, excluding the treatments specified in the exclusion criteria
11. Mild to moderate (from II to III vertex on Hamilton-Norwood scale) androgenetic alopecia
12. Subjects agreeing to preserve a length of hair longer than 5 cm during the study
13. Subjects agreeing to have a zone of about 2 cm^2 shaved on the scalp
14. Willingness to use the same shampoo during all the study period

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Male

Key exclusion criteria
1. Subjects taking part or planning to participate in another clinical trial during the study in the same or another investigation centre
2. Subjects belonging to the staff of the investigation centre
3. Subject who has participated in another clinical trial with anti-hair loss product or treatment within the last 24 weeks before the inclusion visit
4. Subjects with 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
5. Subjects in the course of a long treatment or intending to have one considered by the Investigator liable to interfere with the study data or incompatible with the study requirements
6. Subjects with a skin condition liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
7. Subjects with a personal history of cosmetic, drug or domestic products irritative reactions
8. Inflammatory skin disease or progressive skin lesion on the scalp (psoriasis, seborrheic dermatitis, severe erythema, severe excoriation, severe sunburn, etc)
9. Subjects having a scalp lesion in relief which may be traumatized
10. History of hypersensitivity or intolerance to any of the ingredients in the product formula
11. 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
12. 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
13. Any other local treatment applied on the scalp (non-steroidal anti-inflammatory, ketoconazole) within the last 2 weeks before the inclusion visit
14. Any hair care product applied on the scalp between the last shampoo and the inclusion visit (e.g., gel, hairspray, wax, foam)
15. Radiotherapy, chemotherapy at any time
16. Scalp surgery (hair transplants, laser) at any time

Date of first enrolment
22/11/2021

Date of final enrolment
31/12/2021

Locations

Countries of recruitment

Italy

Study participating centre
Complife Italia Srl
Via Mons. Angelini, 21
San Martino Siccomario (PV)
Italy
27028

Study participating centre
Complife Italia Srl
Corso San Maurizio, 25
Biella
Italy
13900

Study participating centre
Complife Italia Srl
Via Signorelli, 159
Garbagnate Milanese
Italy
20024

Study participating centre
Complife Italia Srl
Piazzale Siena, 11
Milano
Italy
20146

Sponsor information

Organisation
BIONAP srl

Funder(s)

Funder type

Industry

Funder Name
BIONAP srl

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 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 by 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 study director and the person designated by him to elaborate 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