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Improving the efficacy of anti-hair loss drug treatments with a cosmetic lotion containing caffeine, taurine and growth factors

Submission date
18/07/2022

Recruitment status
No longer recruiting

Registration date
18/07/2022

Overall study status
Completed

Last Edited
31/05/2023

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Androgenetic alopecia is a common form of hair loss in both men and women. In men, this condition is also known as male-pattern baldness.
Oral Finasteride 1% and topical minoxidil 2 and 5% are the only two drugs with an approved indication for androgen alopecia (AGA) in men or in women (FAGA), however, both treatments have a response rate of 50-60%.
Concomitant coadjuvant treatments with medical devices or cosmetic products could increase the response rate of anti AGA drugs. GFM-DA is a cosmetic gel to be used once-weekly containing caffeine, taurine and a mixture of growth factors mimicking oligopeptide. So far, there are no controlled data regarding the efficacy of this gel in association with drugs treatment for AGA/FAGA.

Who can participate?
Adults over 18 years with AGA.

What does the study involve?
The study was designed as a randomised, investigator-blinded, prospective trial with 4 arms (one group treated with topical minoxidil 5% twice daily, one group treated with oral finasteride 1 mg orally and two groups with drug (minoxidil or finasteride) plus GFM-DA gel once weekly. The treatments lasted six months (24 weeks). Subjects with AGA/FAGA could participate in the trial. Efficacy evaluation was performed using a colour-high definition global picture of the scalp to perform a Global Photographic Assessment Score (GPAS)(+3 Very good improvement,+2 good improvement;+1 mild improvement; 0: not an improvement; -1 mild worsening; -2 worsening; -3 severe worsening). GPAS was evaluated by comparing the standard photos taken at baseline visit, after 12 weeks and at week 24 by an investigator unaware of treatment arm allocation . The study was conducted in University Dermatology Clinic with specific knowledge of hair loss conditions.

What are the possible benefits and risks of participating?
This trial could offer dermatologists additional clinical evidence regarding the most effective

treatment approach for androgenic alopecia, improving the efficacy outcome of standard pharmacological already approved treatments. No significant risk for participating subjects could be identified.

Where is the study run from?
Ospedale Sant Orsola (Italy)

When is the study starting and how long is it expected to run for?
July 2020 to February 2022

Who is funding the study?
Cantabria Labs (Italy)

Who is the main contact?
Prof Bianca Maria Piraccini

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
GFM-DA-01/2020

Study information

Scientific Title
Efficacy and tolerability of a topical formulation based on growth factors, caffeine and taurine in male subjects with androgenetic alopecia who are candidates for pharmacological treatments (topical minoxidil or oral finasteride): A prospective, randomized, assessor-blinded, parallel group study.

Study objectives
To evaluate if the addition of a cosmetic gel applied once weekly, containing caffeine, taurine and a pool of oligopetides with growth factor mimicking activity could increase the efficacy of standard androgenic alopecia drug treatments such as topical minoxidil or oral finasteride

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/10/2020, Ospedale Sant Orsola University of Bologna (Via Massarenti 1, Bologna, Italy; no telephone number provided; no email provided), ref: GFM-DA-01 Trial

Study design
Interventional prospective randomized 4-arm single-centre assessor-blinded trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet. francesca.starace@unibo.it

Health condition(s) or problem(s) studied
Androgenic alopecia in men or women (FAGA) candidate for specific drug treatment (i.e. topical minoxidil in men or women or oral finasteride in men)

Interventions
The study design included 4 treatment arms:
1. Minoxidil 5% twice daily
2. Minoxidil 5% twice daily plus Investigational cosmetic gel (GFM-DA) once weekly
3. Oral Finasteride 1 mg daily
4. Oral Finasteride 1 mg daily plus Investigational cosmetic gel (GFM -DA) once weekly
The total duration of treatment: 6 months; No follow-up
A randomisation list was generated by a computer

Intervention Type

Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Minoxidil 5% lotion, Finasteride 1 mg tablet, GFM-DA gel

Primary outcome measure
1. Evolution of alopecia using a 7-point Global Photographic Assessement Score (GPAS)(+3 Very good improvement,+2 good improvement;+1 mild improvement; 0: not an improvement; -1 mild worsening; -2 worsening; -3 severe worsening) in the group of GFM-DA treated subjects in comparison with the group of drugs treatment only.
2. GPAS was evaluated by comparing the standard photos taken at baseline visit, after 12 weeks and at week 24 by an investigator unaware of treatment arm allocation

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/07/2020

Completion date
01/02/2022

Eligibility

Key inclusion criteria
1. Men and women >18 years of age
2. Suffering AGA or FAGA requiring drugs treatments (Norwood Hamilton AGA grade III-V)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15 subjects for each arm (60 in total)

Total final enrolment
60

Key exclusion criteria

1. Inflammatory scalp skin condition
2. AGA treatments (finasteride or minoxidil) in the previous 6 months
3. Iron deficiency anaemia
4. Seborrheic dermatitis or scalp psoriasis

Date of first enrolment
07/01/2021

Date of final enrolment
20/11/2021

Locations

Countries of recruitment
Italy

Study participating centre
Ospedale Sant Orsola
Via Massarenti 1
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Sponsor information

Organisation
Difa Cooper (Italy)

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Sponsor type
Industry

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ROR
https://ror.org/044sr7e96

Funder(s)

Funder type
Industry

Funder Name
Cantabria Labs

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/08/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from massimo.milani@difacooper.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/12/2022	31/05/2023	Yes	No