

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

<b>Submission date</b> 18/07/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/07/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/05/2023	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> 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

**Contact name**  
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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 oligopeptides 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 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) 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

Bologna

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## Sponsor information

**Organisation**

Difa Cooper (Italy)

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**Sponsor type**

Industry

**Website**

<http://www.difacooper.com/>

**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](mailto:massimo.milani@difacooper.com)

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		19/12/2022	31/05/2023	Yes	No