

Evaluating the safety and effectiveness of minoxidil (5%) with procapil, redensyl, caffeine & transcutol vs plain minoxidil (5%) in androgenetic alopecia

Submission date 04/12/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/12/2024	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/12/2024	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Androgenetic alopecia (AGA) is a common hair loss condition affecting men and women, impacting confidence and quality of life. This study compares two treatments: plain 5% minoxidil and Mpower™ (5% minoxidil with procapil, redensyl, caffeine, and transcutol). The aim is to assess which treatment is more effective and safe for improving hair growth.

Who can participate?

Adults aged 18 years and above with AGA who have not used other hair loss treatments

What does the study involve?

Participants will be randomly allocated to apply either Mpower™ or plain 5% Minoxidil to their scalp for 4 months. Men will apply it twice daily, and women once at night. Assessments will take place at baseline, 2 and 4 months, including hair growth measurements and satisfaction surveys.

What are the possible benefits and risks of participating?

Participants may experience an improvement in hair growth. Risks include mild side effects like scalp dryness or irritation, which will be monitored.

Where is the study run from?

Zydus Healthcare Limited (India)

When is the study starting and how long is it expected to run for?

September 2023 to October 2024

Who is funding the study?

Zydus Healthcare Limited (India)

Who is the main contact?

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Contact information

Type(s)

Public, Scientific

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Additional identifiers

Protocol serial number

Protocol No. TV/03/09/23

Study information

Scientific Title

An open-label prospective multicentric real-world evidence study to evaluate the safety and effectiveness of minoxidil (5%) with a combination of procapil, redensyl, caffeine, and transcutol vs plain minoxidil (5%) topical solution in study subjects with androgenetic alopecia

Study objectives

MpowerTM (5% minoxidil with procapil, redensyl, caffeine, and transcutol) is more effective and safer than plain 5% minoxidil in improving hair parameters (diameter, vellus hair percentage,

terminal and total hair density), patient satisfaction, tolerability, and compliance in patients with androgenetic alopecia.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 14/09/2023, ACEAS-Independent Ethics Committee (Aradhya, Ambawadi, Ahmedabad, 380015, India; +91 (0)7926460930; iecaceas@gmail.com), ref: Protocol # TV/03/09/23

Study design

Open-label prospective multicentric real-world evidence study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Androgenetic alopecia (AGA)

Interventions

Participants were assigned to treatment groups at the discretion of the treating physicians. It was determined based on clinical judgment and patient suitability for the interventions.

Intervention Arm:

Participants in this group will receive Mpower™, a topical solution containing 5% Minoxidil combined with Procapil, Redensyl, Caffeine, and Transcutol.

Comparator Arm:

Participants in this group will receive plain 5% Minoxidil topical solution.

Participants will be randomly allocated to apply either Mpower™ or plain 5% Minoxidil to their scalp for 4 months. Men will apply it twice daily, and women once at night. Assessments will take place at baseline, 2 and 4 months, including hair growth measurements and satisfaction surveys.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Mpower™ (5% minoxidil with procapil, redensyl, caffeine, and transcutol), plain minoxidil (5% minoxidil solution)

Primary outcome(s)

1. Hair diameter measured using trichoscopic analysis at baseline, 2 and 4 months
2. Terminal hair density evaluated through trichoscopic analysis at baseline, 2 and 4 months (measured in hairs/cm²)

3. Total hair density: assessed via trichoscopy at baseline, 2 and 4 months (measured in hairs/cm²)
4. Vellus hair percentage measured using trichoscopy at baseline, 2 and 4 months

Key secondary outcome(s)

1. Subject satisfaction assessed using the Subject Satisfaction Questionnaire (SSQ) at the end of 4 months
2. Tolerability evaluated based on investigator and participant feedback at 4 months using a four-point scale (excellent, good, fair, poor)
3. Compliance calculated from daily entries in participant diaries, reviewed at 2 and 4 months

Completion date

11/10/2024

Eligibility

Key inclusion criteria

1. Male or female participants aged 18 years and above
2. Participants with a confirmed diagnosis of Androgenetic Alopecia (AGA)
3. Participants eligible to receive topical Minoxidil 5% solutions for the treatment of AGA at the discretion of the treating physician
4. Participants willing to provide written informed consent
5. Participants who have not received any topical or systemic treatment for hair loss prior to enrollment in the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

400

Key exclusion criteria

1. Participants with known hypersensitivity to Minoxidil or any of the ingredients in the test products (MpowerTM or plain minoxidil)
2. Pregnant or breastfeeding females or those planning a pregnancy during the study period
3. Participants with any medical condition that contraindicates the use of minoxidil as determined by the treating physician

4. Participants currently using any other topical or systemic treatments for hair loss
5. Participants with scalp conditions such as inflammation, erythema, infection, irritation, or pain at the application site

Date of first enrolment

15/09/2023

Date of final enrolment

11/06/2024

Locations

Countries of recruitment

India

Study participating centre

Angel Skin Hair Laser Clinic

India

382480

Study participating centre

Arista skin, hair & laser clinic

India

382481

Study participating centre

Dr Seema's skin care and laser center

India

560039

Study participating centre

Nobel hospital

India

380058

Study participating centre

A V Poly Clinic

India

540047

Study participating centre
The Smayan Derma Care
India
380054

Study participating centre
B the change
India
380009

Study participating centre
Dermasculpt Skin and hair transplant clinic
India
560069

Study participating centre
Raghudeep Eye hospital (REH)
India
380052

Study participating centre
Dr Namrata's swastik skin hair and laser clinic
India
380008

Study participating centre
Derma space skin and hair clinic
India
500083

Study participating centre
Uzzaif skincare
India
382210

Study participating centre

Dr Kishan's skin care & Aesthetic research centre

India
560098

Study participating centre
Boss multispeciality hospital

India
560079

Sponsor information

Organisation

Zydus Healthcare Ltd

Funder(s)

Funder type

Industry

Funder Name

Zydus Healthcare Ltd

Results and Publications

Individual participant data (IPD) sharing plan

The data from this study are not expected to be made available. This decision is based on the proprietary nature of the research, the study data captured is deidentified data collected through electronic data capture in the clinical trial management system.

IPD sharing plan summary

Not expected to be made available