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	Prospectively registered
		☐ Protocol
Registration date 10/12/2024	Overall study status Completed	Statistical analysis plan
		Results
Last Edited	Condition category	Individual participant data
06/12/2024	Skin and Connective Tissue Diseases	[X] 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 MpowerTM (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 MpowerTM 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)

Contact information

Type(s)

Public, Scientific

Contact name

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Contact details

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Type(s)

Principal investigator

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

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 MpowerTM, 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 MpowerTM 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)

MPowerTM (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

ΔII

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 coalited through electronic data capture in the clinical trial management system.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type

Details

Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No

Yes