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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

Registration date
10/12/2024

Overall study status
Completed

Last Edited
06/12/2024

Condition category
Skin and Connective Tissue Diseases

[_] 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 (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)

Who is the main contact?
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Contact information

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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

Primary study design
Interventional

Study design
Open-label prospective multicentric real-world evidence study

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/cm^2)

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

IPD sharing plan summary
Not expected to be made available