

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

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

## Plain English Summary

### 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 transcutool). 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?  
Dr Monika Chinda, monika.chinda@zyduslife.com

## Contact information

### Type(s)

Public, Scientific

### Contact name

Dr Prachi Sharma

### Contact details

Digicare Healthcare Solutions Private Limited

Ahmedabad

India

380058

+91 (0)8290799906

patientsafety@tatvacare.in

### Type(s)

Principal Investigator

### Contact name

Dr Khyati Patel

### Contact details

Angel skin hair laser clinic, New Ranip

Ahmedabad

India

382480

+91 (0)9099040705

angelskinclinic@gmail.com

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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 hypothesis**

Mpower™ (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

**Secondary study design**

Non randomised study

**Study setting(s)**

GP practice, Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

**Condition**

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

### **Pharmaceutical study type(s)**

Not Applicable

### **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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

14/09/2023

### **Overall study end date**

11/10/2024

## **Eligibility**

### **Participant 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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

500

**Total final enrolment**

400

**Participant exclusion criteria**

1. Participants with known hypersensitivity to Minoxidil or any of the ingredients in the test products (Mpower™ 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

**Recruitment start date**

15/09/2023

**Recruitment end date**

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

**Sponsor details**  
Zydus Tower CTS No- 460/6 of Village Pahadi  
Off I. B. Patel Road  
Goregaon (East)  
Mumbai  
India  
400063  
+91 (0)9920810337  
Monika.Chinda@zyduslife.com

**Sponsor type**

Industry

**Funder(s)****Funder type**

Industry

**Funder Name**

Zydus Healthcare Ltd

**Results and Publications****Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal

**Intention to publish date**

11/10/2025

**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