Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy and Safety of 2.5 mg versus 5 mg Oral Minoxidil for Androgenetic Alopecia: A Comparative Study

Protocol summary

Study aim

To compare the efficacy and safety of oral minoxidil 2.5 mg versus 5 mg once daily in male patients with androgenetic alopecia.

Design

Two-arm, parallel-group, randomized, double-blind comparative clinical trial conducted at a single center in 58 male patients with androgenetic alopecia. Participants are randomly allocated to receive oral minoxidil 2.5 mg or 5 mg once daily for 6 months, with 29 participants in each group.

Settings and conduct

Participants will receive the assigned oral minoxidil dose once daily for 6 months. They will be followed monthly by clinical examination, blood pressure and heart rate measurement, assessment of lower-extremity edema, and recording of adverse events. Standardized scalp photography and dermoscopy will be performed at baseline and at month 6, and hair density and hair shaft diameter will be assessed using 3D Slicer. The patient and the treating physician are blinded to the dose allocation.

Participants/Inclusion and exclusion criteria

Male patients aged 19–45 years with clinically diagnosed androgenetic alopecia, classified as Hamilton–Norwood grade 1–4, who provide informed consent to participate. Patients with cardiovascular disease, hypotension, renal disease, severe drug hypersensitivity (including TEN, Stevens–Johnson syndrome, or DRESS), or cardiac arrhythmia/non-sinus rhythm on electrocardiography will be excluded.

Intervention groups

Participants will be randomly assigned to two parallel treatment groups. Group 1 will receive oral minoxidil 2.5 mg once daily, and Group 2 will receive oral minoxidil 5 mg once daily for 6 months.

Main outcome variables

Change in hair density and hair shaft diameter and clinical assessment of androgenetic alopecia from baseline to 6 month. Incidence and severity of adverse events during the 6-month treatment period

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220117053743N3**
Registration date: **2026-10-08, 1405/07/16**
Registration timing: **prospective**

Last update: **2026-10-08, 1405/07/16**
Update count: **0**

Registration date

2026-10-08, 1405/07/16

Registrant information

Name

Aida Farmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3261 6408

Email address

aida.farmani.med@gmail.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-20, 1405/08/29

Expected recruitment end date

2028-03-18, 1406/12/28

Actual recruitment start date

2026-11-20, 1405/08/29

Actual recruitment end date

2028-03-18, 1406/12/28

Trial completion date
2028-05-18, 1407/02/29

Scientific title
Efficacy and Safety of 2.5 mg versus 5 mg Oral Minoxidil for Androgenetic Alopecia: A Comparative Study

Public title
Efficacy and Safety of 2.5 mg versus 5 mg Oral Minoxidil for Androgenetic Alopecia: A Comparative Study

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Male patients aged 19–45 years with clinically diagnosed androgenetic alopecia, classified as Hamilton–Norwood grade 1–4, who provide informed consent to participate in the study.

Exclusion criteria:
patients with a history of cardiovascular disease, hypotension, renal disease, severe drug hypersensitivity (TEN, Stevens–Johnson syndrome, or DRESS syndrome), or arrhythmia (non-sinus rhythm on electrocardiography) will be excluded from the study

Age
From **19 years** old to **45 years** old

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **58**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly allocated to two separate groups according to a randomization schedule.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient and the outcome assessor are blinded to the dose allocation.

Placebo
Not used

Assignment
Parallel

Other design features
This is a randomized, double-blind, parallel-group comparative clinical trial conducted in 58 male patients aged 19–45 years with androgenetic alopecia (Hamilton–Norwood grade 1–4). Participants are allocated to receive oral minoxidil 2.5 mg or 5 mg once daily for 6 months. Clinical assessments, blood pressure, heart rate, and lower-extremity edema are monitored monthly. Hair density and hair shaft diameter are assessed at baseline and after 6 months using standardized scalp photography and dermoscopy.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Esfahan University of Medical Sciences

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1234567890

Approval date
2026-05-22, 1405/03/01

Ethics committee reference number
IR.ARI.MUI.REC.1405.072

Health conditions studied

1

Description of health condition studied
Androgenetic Alopecia

ICD-10 code
L64

ICD-10 code description
Androgenic alopecia

Primary outcomes

1

Description
Improvement of hair density

Timepoint
6 month

Method of measurement
Software

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 5mg daily minoxidil

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Individual participant data will not be shared publicly due to privacy and confidentiality considerations. Only aggregated and anonymized study results will be reported in the final publication.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available