Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of topical minoxidil combined with topical finasteride versus topical minoxidil monotherapy in male androgenetic alopecia: single-blind randomized clinical trial

Protocol summary

Study aim
Aim: To assess the effect of topical minoxidil combined with topical finasteride versus topical minoxidil monotherapy in male androgenetic alopecia

Design
This is a Phase III single-blind randomized clinical trial with a control group with parallel groups, in which 32 eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct
This study will be conducted at the Sina Hospital in Hamadan city, involving 32 eligible patients. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be single-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 65 years, Male androgenetic alopecia, Exclusion criteria: History of treatment in the past 6 months, Cardiovascular diseases

Intervention groups
Intervention group: Topical minoxidil 5% plus topical finasteride 0.25% on alopecia location twice daily for 4 months Control group: Topical minoxidil 5% on alopecia location twice daily for 4 months

Main outcome variables
Primary outcome: Average of hair concentration, Average of hair dimeter, Average of hair drop, The rate of patient's satisfaction Secondary outcome: Probable treatment side effects (redness, itching, burning)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N605**
Registration date: **2026-04-21, 1405/02/01**
Registration timing: **prospective**

Last update: **2026-04-21, 1405/02/01**
Update count: **0**

Registration date
2026-04-21, 1405/02/01

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-22, 1405/03/01

Expected recruitment end date
2026-09-23, 1405/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of topical minoxidil combined with topical finasteride versus topical minoxidil monotherapy in male

androgenetic alopecia: single-blind randomized clinical trial

Public title
Effect of topical minoxidil combined with topical finasteride versus topical minoxidil monotherapy in male alopecia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 65 years, Male androgenetic alopecia,
Exclusion criteria:
History of treatment in the past 6 months, Cardiovascular diseases
Age
From **18 years** old to **65 years** old
Gender
Male

Phase
2-3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.
Blinding (investigator's opinion)
Single blinded
Blinding description
The randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. Therefore, the trial will be conducted as a single-blind study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave
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Hamadan
Postal code
6517838695
Approval date
2025-12-13, 1404/09/22
Ethics committee reference number
IR.UMSHA.REC.1404.765

Health conditions studied

1

Description of health condition studied
Androgenic alopecia
ICD-10 code
L64
ICD-10 code description
Androgenic alopecia

Primary outcomes

1

Description
Average of hair concentration
Timepoint
Before the intervention and 4 months later
Method of measurement
Through physical examination

2

Description
Average of hair dimeter
Timepoint
Before the intervention and 4 months later
Method of measurement
Through physical examination

3

Description
Average of hair drop
Timepoint
Before the intervention and 4 months later
Method of measurement
Through physical examination

4

Description
The rate of patient’s satisfaction
Timepoint
4 months after the intervention
Method of measurement
Through 5-choice question in Likert scale

Secondary outcomes

1

Description
Probable treatment side effects (redness, itching, burning)
Timepoint
4 months after the intervention
Method of measurement
Through taking history

Intervention groups

1

Description
Intervention group: Topical minoxidil 5% plus topical finasteride 0.25% on alopecia location twice daily for 4 months
Category
Treatment - Drugs

2

Description
Control group: Topical minoxidil 5% on alopecia location twice daily for 4 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital in Hamadan city
Full name of responsible person
Dr. Alireza Ashraf Abadi
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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
Hamedan 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
Name of organization / entity
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Full name of responsible person
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Position
Resident of Dermatology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available