

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 diameter, 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

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

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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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 diameter

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

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

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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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Alireza Ashraf Abadi

Position

Resident of Dermatology

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for updating data

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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