

# 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)

###### Phone

+98 81 1838 0090

###### Email address

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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

##### City

Hamadan

##### Province

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 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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##### Phone

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##### Email

alireza.ashrafabadi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr. Alireza Soltanian

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Hamadan University of Medical Sciences, Fahmideh Ave

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##### Phone

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info.research@umsha.ac.ir

#### 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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School of Medicine, Hamadan University of Medical Sciences, Fahmideh Ave.

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Bahareh Ebrahimi

**Position**

Dermatologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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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