

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative efficacy study of topical finasteride and topical minoxidil versus topical minoxidil alone in male patients with androgenic alopecia.

#### Protocol summary

##### Study aim

Comparative efficacy of topical finasteride and topical minoxidil versus topical minoxidil alone in androgenic alopecia in men referring to educational center of Isfahan University of medical sciences

##### Design

Clinical trial with control group, with a parallel group, double blind, randomized, phase 3 on 40 patients. Random number table was used for randomization.

##### Settings and conduct

Determining the severity of hair loss by an independent and skilled physician based on the Hamilton and Norwood scale. Counting patients' non-volus hair at the level of 1 cm<sup>2</sup> in a specific area of the scalp (Hair polarizer)(KC Technology). Standardized global photography. Counting the hairs at the end of week 12 and comparing with the number of hairs at the beginning of the study. Evaluation of the patient for hair regrowth at the end of week 12 according to a 7-point scale. Physician evaluation of hair regrowth at the end of week 12 by comparing pre- and post-treatment photographs according to a 7-point scale. The evaluating physician is not aware of the type of treatment performed.

##### Participants/Inclusion and exclusion criteria

Men with moderate to severe androgenic alopecia

##### Intervention groups

The control group received 5% topical minoxidil alone. The experimental group received a topical combination of finasteride 1% and minoxidil 5%.

##### Main outcome variables

Hair count and hair thickness. Standard photographic score reported by the physician. Patient satisfaction score

#### General information

##### Reason for update

##### Acronym

AGA

#### IRCT registration information

IRCT registration number: **IRCT20191203045592N2**

Registration date: **2021-02-10, 1399/11/22**

Registration timing: **prospective**

Last update: **2021-02-10, 1399/11/22**

Update count: **0**

#### Registration date

2021-02-10, 1399/11/22

#### Registrant information

##### Name

Samin Nabavinejad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3131 7715

##### Email address

saminstrs@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-02-19, 1399/12/01

#### Expected recruitment end date

2021-03-05, 1399/12/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparative efficacy study of topical finasteride and topical minoxidil versus topical minoxidil alone in male patients with androgenic alopecia.

## Public title

Comparative efficacy study of topical finasteride in androgenic alopecia

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Men 18-40 years old with moderate to severe androgenic alopecia. Patients should not be treated with oral finasteride or other anti-androgen therapy for the past 6 months. Willingness to participate in the study and fill out the informed consent form. Their diagnosis has been clinically proven and other causes of hair loss have been ruled out.

### Exclusion criteria:

Patients with other types of alopecia such as alopecia areata or telogen effluvium. Any serious systemic disease Receiving systemic treatment for androgenic alopecia during the last 6 months.

## Age

From **18 years** old to **40 years** old

## Gender

Male

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

random number table

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The evaluating physician and patient are not informed about the type of treatment performed on the patient.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

##### Street address

Medical school, Isfahan University of Medical sciences, Hezar Jerib St. Isfahan

## City

Isfahan

## Province

Isfahan

## Postal code

8174673461

## Approval date

2021-01-11, 1399/10/22

## Ethics committee reference number

IR.MUI.MED.REC.1399.909

## 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

Hair count

#### Timepoint

At the start of study and 12 weeks later

#### Method of measurement

Scalp & Hair Polarizing HMS System (KC Technology Company; Korea)

### 2

#### Description

Hair thickness

#### Timepoint

At the start of study and 12 weeks later

#### Method of measurement

Scalp & Hair Polarizing HMS System (KC Technology Company; Korea)

### 3

#### Description

Patient's satisfaction score

#### Timepoint

at the end of 12th week

#### Method of measurement

The standardized 7 point rating scale (-3 = greatly decreased, -2 = moderately decreased, -1 = slightly decreased, 0 = no change, +1 = slightly increased, +2 = moderately increased, +3 = greatly increased)

### 4

#### Description

physician's assessment based on changes in standard photographs

#### Timepoint

at the end of 12th week

#### Method of measurement

The standardized 7 point rating scale (-3 = greatly decreased, -2 = moderately decreased, -1 = slightly decreased, 0 = no change, +1 = slightly increased, +2 = moderately increased, +3 = greatly increased)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Is treated with topical solution of Minoxidil 5% + Finasteride 1% 1 cc twice daily for 12 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Use 1 CC of topical 5% minoxidil lotion (Pakdarou co., Tehran, Iran) applied twice daily for 12 weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Al-Zahra University Hospital

##### Full name of responsible person

Gita Faghihi

##### Street address

Al-Zahra University Hospital, Soffeh Blvd., Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174675731

##### Phone

+98 31 3620 2020

##### Email

alzahra@mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shaghayegh Haghjoueyejavanmard

#### Street address

Medical School, Isfahan University of Medical sciences, Hezar Jerib St., Isfahan

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#### Phone

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#### Email

sh\_haghjoo@med.mui.ac.ir

#### 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

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Gita Faghihi

##### Position

Professor of Dermatology

##### Latest degree

Specialist

##### Other areas of specialty/work

Dermatology

##### Street address

Department of Dermatology, Al-Zahra Hospital, Soffeh Blvd.

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##### Web page address

[https://isid.research.ac.ir/Gita\\_Faghihi](https://isid.research.ac.ir/Gita_Faghihi)

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Samin Nabavinejad

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

No. 301, Shadab complex, Shadab Alley, Bijan Fotouhi Alley, Mohtasham kashani Street

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Samin Nabavinejad

**Position**

Resident

**Latest degree**

Medical doctor

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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