

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### A comparative study of the efficacy and side effects of using oral minoxidil versus topical minoxidil in male pattern androgenetic alopecia patients referring to razi hospital 1401-1402.

#### Protocol summary

##### Study aim

Studying the efficacy and side effects of oral minoxidil on male pattern androgenetic alopecia in comparison with topical minoxidil .

##### Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 50 patients. Patients are randomly assigned to one of two groups based on block randomization.

##### Settings and conduct

Before treatment, the least hair density areas in the frontal, vertex and temporal parts of the scalp are marked by tattoo material by a dermatologist. Before, during and after the treatment , the number of hairs in the same area is measured using a trichoscope. Calculation and comparing is done by taking pictures . The area of minimum density is selected. During the research period, the participants, every month for 3 months and then 6 months after the start of the treatment, in terms of biometric parameters are examined.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: • Age above 18 years • AGA patients based on clinical examination and trichoscopy • male gender • Patients with grade 3 to 5 according to Hamilton's classification for male pattern hair loss  
Exclusion criteria: • Another treatments for hair loss in the last 3 months • Alcohol and drug use • High blood pressure • Heart disease • Allergy to study drugs • Severe liver and kidney diseases • Simultaneous use of other AGA treatments

##### Intervention groups

Case group: Using oral minoxidil at a dose of 2.5 mg to a maximum dose of 5 mg daily . control group: Using topical minoxidil on the scalp area .

##### Main outcome variables

The positive effect of low dose oral minoxidil on male

pattern androgenetic alopecia with no complications .

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221101056366N1**

Registration date: **2023-02-12, 1401/11/23**

Registration timing: **prospective**

Last update: **2023-02-12, 1401/11/23**

Update count: **0**

##### Registration date

2023-02-12, 1401/11/23

##### Registrant information

##### Name

Elham Yousefi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3334 3157

##### Email address

e.yousefi.y@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-19, 1401/11/30

##### Expected recruitment end date

2023-07-22, 1402/04/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

A comparative study of the efficacy and side effects of using oral minoxidil versus topical minoxidil in male pattern androgenetic alopecia patients referring to razi hospital 1401-1402.

## Public title

Studying the effect of oral minoxidil on androgenetic hair loss

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age above 18 years AGA patients based on clinical examination and trichoscopy Male gender Patients with grade3 to 5 according to Hamilton's classification for male pattern hair loss

### Exclusion criteria:

Another treatments for hair loss in the last 3 months  
Alcohol and drug use  
High blood pressure  
Heart disease  
Allergy to study drugs  
Severe liver and kidney diseases  
Simultaneous use of other AGA treatments

## Age

From **18 years** old

## Gender

Male

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

simple randomization was used in this study . In this method simple randomization models like tossing a coin , using randomized number tables, or computerized methods of randomization is used . In this method each case is allocated in one group ( control or intervention) by tossing a coin for example. Some advantages of this method are unpredictability of treatment used for each case. Implementing of this method is simple..

## Blinding (investigator's opinion)

Single blinded

## Blinding description

After entering the study, the participants do not know whether they are in the case or control group, but the doctor does

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

No. 72, block B, unit 6, corner of Sabrian alley, Esfandani street, Tehranpars

##### City

Tehran

##### Province

Tehran

##### Postal code

1654885981

#### Approval date

2022-08-29, 1401/06/07

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.410

## Health conditions studied

### 1

#### Description of health condition studied

Androgenetic alopecia

#### ICD-10 code

L64.9

#### ICD-10 code description

Androgenic alopecia, unspecified

## Primary outcomes

### 1

#### Description

Total hair density, hair thickness, and the total number of vellus and terminal hairs

#### Timepoint

before the start of the study and 1, 2, 3 ,6 months after the start of the study

#### Method of measurement

Using digital video trichoscope and photography

## Secondary outcomes

### 1

#### Description

Total hair density per centimeter square, hair thickness, number of hairs per follicular unit and patient's quality of life based on DLQI

#### Timepoint

1, 2, 3 ,6 months after the initiation of the study

#### Method of measurement

Using a digital video trichoscope

## Intervention groups

### 1

#### Description

Intervention group: 2.5 mg minoxidil tablets, once daily and gradually increasing the dose to twice daily for six months orally

#### Category

Treatment - Drugs

### 2

#### Description

Control group: 5% minoxidil solution once a day for six months topically

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi hospital

##### Full name of responsible person

Elham yousefi

##### Street address

No. 72, Block B, Unit 6, Esfandani Street, TehranPars

##### City

Tehran

##### Province

Tehran

##### Postal code

1654885981

##### Phone

+98 939 546 2948

##### Email

e.yousefi.y@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Maryam nasimi

##### Street address

Tehran University of Medical Sciences, Revolution Square, Porsina St

##### City

Tehran

##### Province

Tehran

##### Postal code

1654885981

##### Phone

+98 912 843 5986

##### Email

nsm.maryam@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tehran 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

Tehran University of Medical Sciences

##### Full name of responsible person

Elham yousefi

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dermatology

##### Street address

No. 72, Block B, Unit 6, Esfandani Street, Tehran Pars

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Maryam nasimi

##### Position

Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dermatology

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Porsina Street, Tehran University of Medical Sciences

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**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam nasimi

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Porsina Street, Tehran University of Medical Sciences

**City**

Tehran

**Province**

Tehran

**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