

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam nasimi

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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

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

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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