Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 patern androgenetic alopecia incomparison 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 effecf 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
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Full name of responsible person
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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
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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