

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of efficacy of 0.5, 2.5 and 5 mg oral minoxidil doses in the treatment of female pattern hair loss

Protocol summary

Study aim

Determination of the effectiveness of 0.5, 2.5 and 5 mg doses of oral minoxidil in the treatment of female pattern androgenic alopecia

Design

Clinical trial with parallel groups, double-blind, randomized with sealed envelopes, phase 2 on 60 patients

Settings and conduct

This study is interventional in which 60 patients with female pattern hair loss referred to the dermatology clinic of Rasoul Akram Hospital are randomly divided into 3 groups A, B and C. For each patient, a questionnaire including demographic and clinical information with sinclair scale will be performed at the beginning of the visit by a dermatologist. Also, in each session, clinical imaging will be performed with the iPhone device as well as dermatoscopy in the frontal and vertex areas. The patient does not know in which treatment group he is. Also, the results are evaluated by a blinded dermatologist and statistical specialist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with clinical diagnosis of female pattern hair loss and Sinclair scale one to four.
Exclusion criteria: patients receiving medication other than vitamins or minerals for alopecia; pregnancy; lactation; abnormal tests.

Intervention groups

Group A patients are given half a milligram daily; group B patients are given two and a half milligrams daily and group C patients are given five milligrams of oral minoxidil daily.

Main outcome variables

Improvement rate with sinclair scale, clinical and dermatoscopic images

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220322054341N1**
Registration date: **2022-04-14, 1401/01/25**
Registration timing: **prospective**

Last update: **2022-04-14, 1401/01/25**

Update count: **0**

Registration date

2022-04-14, 1401/01/25

Registrant information

Name

masoumeh roohaninasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2421

Email address

rohaninasab.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of 0.5, 2.5 and 5 mg oral minoxidil doses in the treatment of female pattern hair loss

Public title

Comparison of the effect of 0.5, 2.5 and 5 mg doses of oral minoxidil in the treatment of female pattern of hereditary hormonal hair loss

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with clinical diagnosis of female pattern hair loss
Sinclair scale one to four
Age range 18 to 50 years old
Conscious consent to enter the study and the possibility of attending visits and follow-up sessions

Exclusion criteria:

Patients taking medication other than vitamins or minerals for alopecia
Pregnancy or breastfeeding
Patients with serious internal disease, especially heart disease or comorbidities at the treatment site
Psychiatric patients
Abnormal tests at baseline

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a simple randomization method, patients who refer to the dermatology clinic of Rasoul Akram Hospital are divided into three groups, so that out of 60 sealed bags, one bag is randomly selected for each patient. Each letter contains A, B, or C. Group A patients are given half a milligram daily, group B patients are given two and a half milligrams daily, and group C patients are given five milligrams of oral minoxidil daily.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient does not know in which treatment group he is. Also, the results are evaluated by a blinded dermatologist and the data is analyzed by a blinded statistical specialist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of School of Medicine, Iran University of medical sciences

Street address

School of medicine, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-11-29, 1400/09/08

Ethics committee reference number

IR.IUMS.FMD.REC.1400.520

Health conditions studied

1

Description of health condition studied

Female pattern androgenic alopecia

ICD-10 code

L64

ICD-10 code description

Androgenic alopecia

Primary outcomes

1

Description

Improvement rate

Timepoint

3 and 6 months after starting treatment

Method of measurement

By sinclair scale, clinical and dermatoscopic images (Determine the number and thickness of hair shafts per square centimeter)

Secondary outcomes

1

Description

Safety

Timepoint

3 and 6 months after starting treatment

Method of measurement

Asking the patient about the side effects of treatment

2

Description

Tolerability

Timepoint

3 and 6 months after starting treatment

Method of measurement

With Investigator Assessment of Tolerability scale (zero, low, medium and high or sufficient)

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3

Description

Patient satisfaction

Timepoint

3 and 6 months after starting treatment

Method of measurement

With Caregiver treatment satisfaction (CTS) questionnaire (completely satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied and completely dissatisfied)

Intervention groups

1

Description

Intervention group A: half a milligram of oral minoxidil daily for 6 months

Category

Treatment - Drugs

2

Description

Intervention group B: two and a half milligrams of oral minoxidil daily for 6 months

Category

Treatment - Drugs

3

Description

Intervention group C: five milligrams of oral minoxidil daily for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram hospital

Full name of responsible person

Masoomeh Rohaninasab

Street address

Hazrat Rasool Akram hospital, Mansoori avenue, Sattarkhan street, Tehran, Iran

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Email

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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Masoomeh Roohaninasab

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

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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

Not applicable