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)

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+98 21 6435 2421

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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)

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
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
Masoumeh Roohaninasab
Position
Assistant professor
Latest degree
Specialist
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
Not applicable