Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effectiveness of topical and oral Minoxidil in the treatment of androgenic alopecia

Protocol summary

Study aim
This study aimed to compare the effect of topical and oral minoxidil in the treatment of androgenic alopecia.

Design
A clinical trial with a control group, blinded outcome assessment, randomized, phase 3 on 60 patients. Random allocation software was used for randomization.

Settings and conduct
This study will be performed in Isfahan Al-Zahra Hospital and clinics affiliated with Isfahan University of Medical Sciences. Images of the vortex at 12, 16, and 24 centimeters distances from Glabla are recorded in all patients with a standard global camera and dermoscopy with 20x magnification and polarized light at the beginning of the intervention and three months and six mon. Patients' evaluation is based on images. two dermatologists will score the changes in hair density between images from zero to ten.

Participants/Inclusion and exclusion criteria
Inclusion criteria: androgenic alopecia patients who are in the clinical examination according to Hamilton and Norwood system in grade 2-4 with male pattern alopecia and Ludwig system in grade 1-2 with the female pattern. Exclusion criteria: cardiovascular disease; hypotension; history of drug allergy; pregnancy; lactation.

Intervention groups
Intervention group: patients take one mg of minoxidil capsules daily for six months. Control group: patients spray 8 puffs of 5% minoxidil solution on the scalp once a day.

Main outcome variables
Change in hair density

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220117053743N1**
Registration date: **2022-03-11, 1400/12/20**
Registration timing: **prospective**

Last update: **2022-03-11, 1400/12/20**
Update count: **0**

Registration date
2022-03-11, 1400/12/20

Registrant information

Name
Aida Farmani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3261 6408

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aida.farmani.med@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-04, 1401/01/15

Expected recruitment end date
2022-10-07, 1401/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of topical and oral Minoxidil in the treatment of androgenic alopecia

Public title
Effect of oral minoxidil in treatment of androgenic alopecia

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with male pattern alopecia according to Hamilton and Norwood system are in grade 2-4 Patients with Female pattern alopecia according to the Ludwig system are in grade 1-2
Exclusion criteria:
Cardiovascular disease and hypotension Kidney Diseases History of drug allergy Pregnancy Lactation
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly divided into two separate groups by random allocation software
Blinding (investigator's opinion)
Single blinded
Blinding description
The outcome assessor and data analyst are unaware of the intervention
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezarjarib street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-12-25, 1400/10/04
Ethics committee reference number
IR.MUI.MED.REC.1400.712

Health conditions studied

1

Description of health condition studied
Androgenic alopecia
ICD-10 code
L64
ICD-10 code description
Androgenic alopecia

Primary outcomes

1

Description
Standardized global photography
Timepoint
Before the start of the study and 3, 6 months after the start of the intervention
Method of measurement
Based on scoring by two dermatologist

2

Description
Dermoscopy imaging
Timepoint
Before the start of the study and 3, 6 months after the start of the intervention
Method of measurement
Based on scoring by two dermatologist

Secondary outcomes

1

Description
Change in hair density
Timepoint
At the beginning of the study (before the intervention) and 3, 6 months after the intervention
Method of measurement
Scoring by two dermatologists

Intervention groups

1

Description
Intervention group: A group of 30 patients will be administered with minoxidil capsules at a dose of one milligram per day for six months
Category
Treatment - Drugs

2

Description
Control group: A group of 30 patients will be treated with 5% topical minoxidil eight puffs a day for six months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Dr. Aida Farmani
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Dermatology Department, Alzahra hospital, Sofe street, Isfahan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Mansour Siavash
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Aida Farmani
Position
Dermatology Resident
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
All data is potentially shareable after unidentifiable individuals

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Everyone

Under which criteria data/document could be used
No limitations

From where data/document is obtainable
Dr. Aida Farmani 00989134090453

What processes are involved for a request to access data/document
By phone, the data will send up to two weeks later

Comments