

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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 Glabella 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)

Phone

+98 31 3261 6408

Email address

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

Isfahan

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

Street address

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

Street address

Isfahan University of Medical Sciences, Isfahan, Iran

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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

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Position

Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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