

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

A triple-blind randomized clinical trial on the effectiveness of oral minoxidil in the treatment of women with Androgenetic Alopecia

Protocol summary

Study aim

Comparison of the therapeutic effects of Oral Minoxidil Tablets in dose of 0.25 mg with topical Minoxidil Therapeutic Effects in woman Patients with Androgenic Alopecia

Design

Patients are subjected to weekly intervals up to one month, then monthly for up to three months, and then every three months for visits under necessary trials. At the end of one year, the therapeutic effects of the two groups based on the three criteria of Sinclair scale, shedding scale and Trichoscopy and the side effects of each drug will be assessed.

Settings and conduct

Patients referred to Dermatology Clinic of Imam Reza Hospital and Ghaem Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 18 to 50 with androgenetic alopecia of female pattern (with Sinclair stage 2-5) Non-compliance criteria: • Other causes of hair loss, including inflammatory and cicatricial hair loss • The presence of other symptoms of hyperandrogenism (in particular, malaise and hirsutism) • Severe systemic disease (cardiovascular - renal - hepatic) • History of pressure drop or baseline blood pressure less than 60/90 mmHg • The patient's desire for pregnancy during one year of study • Use of any effective medication on alopecia, including hormonal medications

Intervention groups

The selected patients were randomly divided into two groups and the first group (30 patients) daily received oral minoxidil (0.25 mg) and topical placebo (one cc twice daily) . The second one (30 patients) treated with topical minoxidil (One cc of 2% solution twice a day) and oral placebo.

Main outcome variables

Hair loss condition based on Sinclair scale and shedding scale Study of density and thickness of hair by trichoscopy Measurement time: every 3 months

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181011041311N1**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

Registration date

2019-03-09, 1397/12/18

Registrant information

Name

Vahideh Sabeti

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3849 4720

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A triple-blind randomized clinical trial on the effectiveness of oral minoxidil in the treatment of women with Androgenetic Alopecia

Public title

The effectiveness of oral minoxidil in women with scalp hair loss

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with female pattern hair loss androgenic alopecia (with Sinclair stage between 2 and 5) based on clinical diagnosis and histopathology Age: between 18 and 50

Exclusion criteria:

Other causes of hair loss, including inflammatory and cicatricial hair loss The presence of other symptoms of hyperandrogenism (in particular, malaise and hirsutism), which is also evident in laboratory examination of hormonal disorders supported by polycystic ovaries, ovarian and adrenal tumors. Severe systemic disease (cardiovascular - renal - hepatic) A history of pressure drop or blood pressure less than 90/60 mmHg The patient's desire for pregnancy during one year is under study Taking any effective medication for alopecia, including hormonal medications

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyst

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: blocked This method is used to prevent significant imbalances in the number of participants assigned to each group. Allocation Concealment: Sealed envelopes The method used to generate a random assignment sequence: A random number table using www.randomization.com

Blinding (investigator's opinion)

Triple blinded

Blinding description

Individuals under study, evaluators and analysts will be unaware of the intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Opposite to Daneshgah 18 St, Mashhad University of Medical Sciences, Deputy of Research and Technology of the University

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Mashhad

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Razavi Khorasan

Postal code

9137913316

Approval date

2018-11-13, 1397/08/22

Ethics committee reference number

ir.mums.medical.rec.1397.536

Health conditions studied

1

Description of health condition studied

Female pattern hair loss (FPHL) androgenic alopecia

ICD-10 code

L64

ICD-10 code description

Androgenic alopecia

Primary outcomes

1

Description

Hair loss condition

Timepoint

Every 3 months

Method of measurement

based on Sinclair scale and shedding scale

2

Description

evaluating the density and thickness of the hair

Timepoint

Every 3 months

Method of measurement

By trichoscopy

Secondary outcomes

1

Description

Blood pressure, weight

Timepoint

Weekly up to one month then monthly up to three months and then every three months

Method of measurement

Pressure gauge cuff, Weight gauge

2

Description

liver, renal and electrolyte tests

Timepoint

The third and 12th month after starting treatment

Method of measurement

Blood sampling

Intervention groups

1

Description

Intervention group: Daily treatment with Oral Minoxidil Tablets (0.25 mg) and topical Placebo (1 CC twice a day) for one year

Category

Treatment - Drugs

2

Description

Control group: Daily treatment with topical minoxidil (1 cc of 2% solution twice daily) and oral placebo for one year

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Imam Reza Hospital Hospital in Mashhad

Full name of responsible person

Dr Sadegh Vahabi Amlashi

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The beginning of Daneshgah St, Mashhad, Imam Reza Hospital

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

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Web page address

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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

Mashhad 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
Mashhad University of Medical Sciences
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Position
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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

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are made
unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are
published.

To whom data/document is available

Data will be available for researchers in universities and
other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through sending an email to the
corresponding author.

What processes are involved for a request to access data/document

After sending a request email to the corresponding
author, data will be sent in 1 month.

Comments