# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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)

**Phone**

+98 51 3849 4720

**Email address**

sabetiv@yahoo.com

**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 alopcia ( with sinclair stgae 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 analyser

**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
**City**
Mashhad
**Province**
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 alopcia
**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

**Street address**

The beginning of Daneshgah St, Mashhad, Imam Reza Hospital

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3802 5726

**Email**

emamreza@mums.ac.ir

**Web page address**

http://emamreza.mums.ac.ir/

**2**

**Recruitment center**

**Name of recruitment center**

Dermatology Clinic of Ghaem Hospital in Mashhad

**Full name of responsible person**

Dr Sadegh Vahabi Amlashi

**Street address**

Ahmadabad St, Mashhad, GHaem Hospital

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91766-99199

**Phone**

+98 51 3840 0000

**Fax**

+98 51 3845 3239

**Email**

Quaem.Medical.Center@mums.ac.ir

**Web page address**

http://quaem.mums.ac.ir/index.php

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3841 2081

**Fax**

+98 51 3843 0249

**Email**

vcresearch@mums.ac.ir

**Web page address**

http://v-research.mums.ac.ir/index.php

**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

**Full name of responsible person**

Vahideh Saabeti

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

No B42, Kohansangi Residential Complex, Koohsangi 15 Ave, Koohsangi St

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176774448

**Phone**

+98 51 3849 4720

**Email**

sabetiv@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr sadegh Vahabi Amlashi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

daneshgah st, Imam Reza hospital, Dermatology department

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51385430319

**Email**

VahabiS@mums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Vahideh Sabeti

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

NO B42, Kohansangi Residential Complex, Koohsangi15 Ave, Koohsangi St

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176774448

**Phone**

+98 51 3849 4720

**Email**

sabetiv@yahoo.com

## 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**