

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Randomized Clinical Trial Comparing 5% Topical Minoxidil and 5% Topical Minoxidil plus Topical Betamethasone for the Treatment of Androgenetic Alopecia in Iranian Men

#### Protocol summary

##### Summary

The purpose of this study is to compare the effect of topical minoxidil plus betamethasone versus topical minoxidil in patients with androgenetic alopecia. sixty subjects with androgenetic alopecia will be enrolled in the study and randomized to two equal groups. At the first visit a biopsy specimen and photograph will be taken from the scalp. the treatment will be initiated. every 4 weeks for 6 months they will be visited and photograph will be taken for comparison. subjects with the ages more than 25 and less than 40 will be enrolled in the study. Patients using drugs such as non-steroidal anti-inflammatory drugs; antiseptics and anti-fungal and anti-hypertensive will be excluded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016031727095N1**

Registration date: **2016-05-24, 1395/03/04**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-24, 1395/03/04

##### Registrant information

###### Name

Arash Bagheri Hamidi

###### Name of organization / entity

Shahid beheshti university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 88267994

##### Email address

arash.bagherihamidi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Beheshti University of Medical Sciences and Health Services

##### Expected recruitment start date

2016-04-03, 1395/01/15

##### Expected recruitment end date

2017-04-04, 1396/01/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Randomized Clinical Trial Comparing 5% Topical Minoxidil and 5% Topical Minoxidil plus Topical Betamethasone for the Treatment of Androgenetic Alopecia in Iranian Men

##### Public title

The effect of topical minoxidil plus betamethasone on androgenetic alopecia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: Androgenetic alopecia; Age 25 and more; Age less than 40 Exclusion criteria: using of corticosteroids; NSAIDs; Cytotoxic agents; topical antiseptics and anti fungals; vasodilators; antibiotics; anti hypertensive medications; diuretics; spirinolactone; cimetidine; cyclosporin; finasteride; ketoconazole

##### Age

From **25 years** old to **40 years** old

**Gender**

Male

**Phase**

3

**Groups that have been masked***No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees**1**Ethics committee****Name of ethics committee**

Shahid Beheshti University of Medical Sciences and Health Services

**Street address**

Velenjak St., Chamran Highway

**City**

Tehran

**Postal code****Approval date**

2016-01-21, 1394/11/01

**Ethics committee reference number**

IR.SBMU.SRC.REC.1394.11

**Health conditions studied**1**Description of health condition studied**

Androgenetic Alopecia

**ICD-10 code**

L64

**ICD-10 code description**

male-pattern baldness

**Primary outcomes**1**Description**

hair growing

**Timepoint**

2 months

**Method of measurement**

Trichoscopy

**Secondary outcomes**

empty

**Intervention groups**1**Description**

In the first visit we will take a biopsy specimen from scalp for routine histopathological studies. A 2\*2 centimeters area of scalp will be photographed by a trichoscope for the purpose of counting. This group will receive topical 5% minoxidil plus betamethasone (0.1%) (45 milliliters) plus 70-degree alcohol up to 100 milliliters. The subjects will be visited every 4 weeks for 6 months. At each visit, their hairs will be photographed for the purposes of counting and comparing with previous photographs. After six month of initiating treatment subjects will be asked to discontinue therapy for 3 months and pattern and rate of hair loss will be analyzed.

**Category**

Treatment - Drugs

2**Description**

In the first visit we will take a biopsy specimen from scalp for routine histopathological studies. A 2\*2 centimeters area of scalp will be photographed by a trichoscope for the purpose of counting. This group will receive topical 5% minoxidil. The subjects will be visited every 4 weeks for 6 months. At each visit, their hairs will be photographed for the purposes of counting and comparing with previous photographs. After six month of initiating treatment subjects will be asked to discontinue therapy for 3 months and pattern and rate of hair loss will be analyzed.

**Category**

Treatment - Drugs

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Loghman Hakim hospital

**Full name of responsible person**

Dr Mehdi Gheysari

**Street address**

Qazvin St., South Kargar Ave.

**City**

Tehran

2**Recruitment center**

**Name of recruitment center**  
Shohadaye Tajrish Educational Hospital  
**Full name of responsible person**  
Dr Mehdi Gheysari  
**Street address**  
Tajrish Sq., Tehran, Iran  
**City**  
Tehran

**Fax**  
+98 21 5541 7547  
**Email**  
arash.bagheri@gmail.com  
**Web page address**

## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences and Health Services  
**Full name of responsible person**  
Dr Mehdi Gheysari  
**Position**  
Dermatology specialist  
**Other areas of specialty/work**  
**Street address**  
Qazvin St., South kargar Ave., Loghman Hakim hospital  
**City**  
Tehran  
**Postal code**  
**Phone**  
+98 21 5541 9005  
**Fax**  
**Email**  
arash.bagherihamidi@gmail.com  
**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences and Health Services  
**Full name of responsible person**  
Dr Mehdi Gheysari  
**Street address**  
Velenjak Street, Chamran highway  
**City**  
Tehran  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Shahid Beheshti University of Medical Sciences and Health Services  
**Proportion provided by this source**  
100  
**Public or private sector**  
*empty*  
**Domestic or foreign origin**  
*empty*  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences and Health Services  
**Full name of responsible person**  
Dr Mehdi Gheysari  
**Position**  
Assistant professor/Dermatology specialist  
**Other areas of specialty/work**  
**Street address**  
Qazvin St, South Kargar Ave, Loghman Hakim Hospital  
**City**  
Tehran  
**Postal code**  
**Phone**  
+98 21 5541 9005

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences and Health Services  
**Full name of responsible person**  
Dr Mehdi Gheysari  
**Position**  
Dermatology Specialist/assistant proffesor  
**Other areas of specialty/work**  
**Street address**  
Makhsoos St, South Karegar Ave, Loghman Hakim hospital  
**City**  
Tehran  
**Postal code**  
**Phone**  
+98 21 5541 9005  
**Fax**  
+98 21 5541 7547  
**Email**  
**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**

*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*

**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*