

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of topical herbal preparation with minoxidil in androgenic alopecia: double blind randomized clinical trial

#### Protocol summary

##### Study aim

Comparing the efficacy of topical herbal preparation and minoxidil on androgenic alopecia in the male patients referred to Imam Reza hospital dermatology clinic

##### Design

Double-blind clinical trial, with parallel groups, randomized, phase I on 60 patients, with a 4-block randomization method will be randomized

##### Settings and conduct

This double-blind clinical trial will be done in Mashhad Imam Reza hospital and patients with androgenic alopecia will be randomly divided into groups receiving topical herbal preparation (containing extracts of Adiantum capillus-veneris 1%, Phyllanthus emblica 5%, Centella asiatica 0.5%, Ruta graveolens 0.5%) and topical minoxidil 5%. Trichoscopy and self-assessment parameters by patients will be evaluated at baseline and end of the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Male patient between 18-45 y/o Androgenic alopecia grade 3-6 base on hamilton-norwood scale system Patient satisfaction Exclusion criteria: Diabetes , thyroide dysfunction and other endocrine disease Using supplement including iron & zinc Renal disease,malnutrition,iron deficiency anemia, systemic disease such as lupus, other cause of alopecia including areata or cicatricial alopecia, Using Medication can cause hair loss including antihypertensive drug , NSAID History of dermatologic or systemic malignancy Psychologic disorders Drug or alcohole abuse History of finastride treatment in past 6 month

##### Intervention groups

Group 1 (control): will receive standard treatment: topical minoxidil Group 2 (intervention): will receive topical herbal preparation

##### Main outcome variables

Hair count

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220626055283N1**

Registration date: **2022-11-30, 1401/09/09**

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

Last update: **2022-11-30, 1401/09/09**

Update count: **0**

##### Registration date

2022-11-30, 1401/09/09

##### Registrant information

##### Name

Mahdieh Toosi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3723 6716

##### Email address

tousimh991@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-11, 1401/08/20

##### Expected recruitment end date

2023-11-11, 1402/08/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of topical herbal preparation with minoxidil in androgenic alopecia: double blind randomized clinical trial

#### **Public title**

Efficacy of herbal solution in androgenic alopecia treatment

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

All male patient between 18-45 years old with androgenic alopecia Patient satisfaction

##### **Exclusion criteria:**

Endocrine disorder Using zinc and iron supplement Renal disease Malnutrition and iron deficiency anemia Thyroid disorder Systemic disorder such as lupus Other causes of alopecia like alopecia areata and scar alopecias Using drugs lead to alopecia like anti-hypertensive agents or NSAIDs History of dermatologic or systemic malignancy Psychiatric disorders Consumption of alcohol History of consumption of finasteride within 6 months ago

#### **Age**

From **18 years** old to **45 years** old

#### **Gender**

Male

#### **Phase**

1

#### **Groups that have been masked**

- Participant
- Outcome assessor

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Patients will be allocated to topical herbal preparation or topical minoxidil groups, by block randomization with a block size of 4. In each block, patients of each group will exist. The order of blocks will be determined randomly in topical herbal preparation or topical minoxidil groups and subjects will be allocated sequentially with the order of admitting. The random allocation rule method was used for the determination of sequences. Use non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

Patients receive drugs (intervention or control groups) in closed pockets which are coded and patients are not aware of their contents. Coding will be done by one of

the colleagues of the study and the investigator physician will be blind for the type of drugs.

#### **Placebo**

Not 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**

Central Building of Mashhad University of Medical Sciences (Ghorashi), Daneshgah 16, Daneshgah street

###### **City**

Mashhad

###### **Province**

Razavi Khorasan

###### **Postal code**

9177899191

##### **Approval date**

2017-12-20, 1396/09/29

##### **Ethics committee reference number**

IR.MUMS.fm.REC.1396.602

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Male androgenic alopecia

##### **ICD-10 code**

L64.9

##### **ICD-10 code description**

Androgenic alopecia, unspecified

### **Primary outcomes**

#### **1**

##### **Description**

Hair count

##### **Timepoint**

Evaluation of hair count with trichoscopy in 0, 8, 16, 24 weeks of trial

##### **Method of measurement**

Efficacy of herbal solution (Adiantum Capillus-veneris, Centella asiatica, Rutagraveolense, Emblica officinalis) on androgenic alopecia and examine hair count with trichoscopy

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group:Receiving topical herbal preparation (containing extracts of Adiantum capillus-veneris 1%, Centella asiatica 0.5%, Ruta graveolense 0.5%, Emblica officinalis 5%)

### Category

Treatment - Drugs

2

### Description

Intervention group: Receiving topical minoxidil 5%

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Dermatology clinic of Mashhad Imam Reza hospital

#### Full name of responsible person

Bitia Kiafar

#### Street address

Dermatology department, Imam Reza hospital, Imam Reza hospital square, AVECINA street, Imam Reza hospital square, Mashhad

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9137913316

#### Phone

+98 51 3802 2031

#### Email

Tousimh991@mums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Dr majid ghayour

#### Street address

Third Floor, Ghoreshi Building, Daneshgah Street, Shariati Square, Mashhad

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9138813944

#### Phone

+98 51 3841 1538

#### Fax

#### Email

Ramresearch@mums.ac.ir

### 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

Seyedeh Mahdieh Toosi

#### Position

Resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Dermatology

#### Street address

Dermatology department, Imam Reza hospital, Imam Reza hospital square, AVECINA street, Imam Reza hospital square, Mashhad

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9177899191

#### Phone

+98 51 3802 2031

#### Email

Tousimh991@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Bitia kiafar

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Dermatology department, Imam Reza hospital, Imam Reza hospital square, AVECINA street, Imam Reza hospital square, Mashhad

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Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

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+98 51 3802 2031

**Email**

Kiafarb@mums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Amin Saeidinia

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Pharmaceutical Sciences Phd by research

**Street address**

Fifth floor, Akbar hospital, Kaveh Boulevard, Javan Square, Mahhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177897157

**Phone**

+98 51 3871 3801

**Email**

saeidinia971@mums.ac.ir

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more data

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not 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**

Data of clinical trial in analysis will be published in an article after blinding patients' data

**When the data will become available and for how long**

Unlimited from publishing

**To whom data/document is available**

Researchers in medical universities

**Under which criteria data/document could be used**

Data are specific for this study and is not reusable

**From where data/document is obtainable**

Request by email to the corresponding author recorded in this registry Dr. Bitia Kiafar Email: Kiafarb@mums.ac.ir Tel: +985138022031 Address: Dermatology department, Imam Reza hospital, Imam Reza hospital square, AVECINA street, Imam Reza hospital square, Mashhad

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

Sending a formal request with details of the needed information to the email of the person responsible for scientific inquiries. Then it will be responded to after one week by the person responsible for scientific inquiries.

**Comments**