

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 2026

### Clinical evaluation of the safety and effectiveness Oral capsules (containing minoxidil, finasteride and biotin) in the prevention and treatment of androgenic hair loss

#### Protocol summary

##### Study aim

Clinical evaluation of the safety and effectiveness Oral capsules (containing minoxidil, finasteride and biotin) in the prevention and treatment of androgenic hair loss

##### Design

Single group, phase 2, before -after clinical study. sample size is 20. The study is not randomized.

##### Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy, 20 healthy volunteers will be selected and enrolled in the study after signing consent form. Volunteers are taught to use Oral capsules (containing minoxidil, finasteride and biotin) once a day for 16 weeks. Before intervention and at the end of 8 and 16 weeks later changing in hair lost will be measured.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Male aged 18-50 years, General health, Hair Loss Status II, III, IV Based on Norwood Scale, Voluntary participation and signing written informed consent Exclusion criteria: Chronic active scalp disease other than hair loss, Using any prescribed drug or OTC for hair loss within the past 3 months, Documented sensitivity to formulation components, Any severe weight loss or strict diet therapy during the study

##### Intervention groups

Intervention group: Daily use of oral anti-hair loss capsules containing 5 mg of biotin, 1 mg of finasteride, 1 mg of minoxidil as active ingredients more over lactose monohydrate as oxyplan, for 16 weeks

##### Main outcome variables

Hair lost Changes, based on Global photographic review

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20190210042676N18**

Registration date: **2022-02-08, 1400/11/19**

Registration timing: **prospective**

Last update: **2022-02-08, 1400/11/19**

Update count: **0**

#### Registration date

2022-02-08, 1400/11/19

#### Registrant information

##### Name

Aniseh Samadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8897 2220

##### Email address

a\_samadi@razi.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2022-02-19, 1400/11/30

#### Expected recruitment end date

2022-09-21, 1401/06/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Clinical evaluation of the safety and effectiveness Oral capsules (containing minoxidil, finasteride and biotin) in

the prevention and treatment of androgenic hair loss

**Public title**  
Clinical evaluation of the safety and effectiveness Oral capsules in the prevention and treatment of hair loss

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Male aged 18-50 years General health Hair Loss Status II, III, IV Based on Norwood Scale Voluntary participation and signing written informed consent  
**Exclusion criteria:**  
Chronic active scalp disease other than hair loss Using any prescribed drug or OTC for hair loss within the past 3 months Documented sensitivity to formulation components Any severe weight loss or strict diet therapy during the study

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

**Gender**  
Male

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **20**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

Research and Technology Dept, 6th floor, Central Organization of the University, Ghods St., Keshavarz Blvd.

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

#### Approval date

2022-01-15, 1400/10/25

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1214

## Health conditions studied

### 1

#### Description of health condition studied

hair loss

#### ICD-10 code

L65.9

#### ICD-10 code description

Nonscarring hair loss, unspecified

## Primary outcomes

### 1

#### Description

Hair lost Changes, based on Global photographic review

#### Timepoint

Before intervention, 8 and 16 weeks after the start of use

#### Method of measurement

One independent dermatologist will perform clinical assessments in a blinded fashion by scoring every photograph according to the Global photographic review scale .

## Secondary outcomes

### 1

#### Description

Hair count changes

#### Timepoint

Before intervention, 8 and 16 weeks after the start of use

#### Method of measurement

Trichoscopy By Fotofinder

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: Daily use of oral anti-hair loos capsules containing 5 mg of biotin, 1 mg of finasteride, 1 mg of minoxidil as active ingredients more over lactose monohydrate as oxyplan, for 16 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Center for research and training in skin diseases and leprosy

**Full name of responsible person**

Aniseh Samadi

**Street address**

No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

1416613675

**Phone**

+98 21 8897 0658

**Email**

dermalab@tums.ac.ir

**Position**

manager of Clinical Laboratory

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Dermatology

**Street address**

No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

1416613675

**Phone**

+98 21 8897 0658

**Email**

aniseh\_samadi@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Knowledge-based company of Janus

**Full name of responsible person**

Saman Ahmad Nasrollahi

**Street address**

No. 415, Shahid Naderi St., Taleqani Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

1416613675

**Phone**

+98 21 8896 2981

**Email**

headoffice@januspharma.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Knowledge-based company of Janus

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Persons

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Aniseh Samadi

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Alireza Firooz

**Position**

Proffesor of Dermatology

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

1416613675

**Phone**

+98 21 8897 7921

**Email**

firozali@sina.tums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Ahmadi

**Position**

Research Expert

**Latest degree**

Master

**Other areas of specialty/work**

Dermatology

**Street address**

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1416613675  
**Phone**  
+98 21 8897 0658  
**Email**  
ahmadi.maryam648@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Undecided - It is not yet known if there will be a plan to

make this available  
**Study Protocol**  
Undecided - It is not yet known if there will be a plan to make this available  
**Statistical Analysis Plan**  
Not applicable  
**Informed Consent Form**  
Undecided - It is not yet known if there will be a plan to make this available  
**Clinical Study Report**  
Undecided - It is not yet known if there will be a plan to make this available  
**Analytic Code**  
Not applicable  
**Data Dictionary**  
Not applicable