

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Evaluation of safety and the effectiveness of Caffeine Plus Irox anti-hair loss line (serum and shampoo) produced by Iran Avandfar company In the prevention and treatment of androgenic hair loss

#### Protocol summary

##### Study aim

Evaluation of safety and the effectiveness of Caffeine Plus Irox anti-hair loss serum and shampoo produced by Iran Avandfar company 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 will be taught to use Caffeine Plus Irox anti-hair loss serum once a day for 12 weeks and Caffeine Plus Irox anti-hair loss shampoo for hair washing. Before intervention and at the end of 6 and 12 weeks later changing in hair lost will be measured. This study is not blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Male aged 18-55 years, Good general health, Voluntary participation and signing written informed consent, Hair Loss Status II, III, IV based on Norwood Scale Exclusion criteria: Chronic active scalp disease other than hair loss, Using any prescribed drug or OTC for hair loss within the past 3 months, People with allergies to serum and shampoo ingredients, Any severe weight loss, or strict diet therapy during the study

##### Intervention groups

A- Topical use of Caffeine Plus Irox anti-hair loss serum produced by Iran Avandfar company 20 drops once a day, for 12 weeks. B- Topical use of Caffeine Plus Irox anti-hair loss shampoo produced by Iran Avandfar company at least three times a week, for 12 weeks.

##### Main outcome variables

Hair lost changes, based on Global photographic review

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190210042676N13**

Registration date: **2021-05-08, 1400/02/18**

Registration timing: **prospective**

Last update: **2021-05-08, 1400/02/18**

Update count: **0**

##### Registration date

2021-05-08, 1400/02/18

##### 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

2021-05-15, 1400/02/25

##### Expected recruitment end date

2021-11-16, 1400/08/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of safety and the effectiveness of Caffeine Plus Irox anti-hair loss line (serum and shampoo) produced by Iran Avandfar company In the prevention and treatment of androgenic hair loss

## Public title

Evaluation of safety and the effectiveness of Caffeine Plus Irox anti-hair loss serum and shampoo

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Male aged 18-55 years Good general health Voluntary participation and sign the written informed consent Hair Loss Status II, III, IV based on Norwood Scale

### Exclusion criteria:

Chronic active scalp disease other than hair loss Using any prescribed drug or OTC for hair loss within the past 3 months People with allergies to serum and shampoo ingredients 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

2021-03-07, 1399/12/17

## Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.1223

## 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, 6 and 12 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, 6 and 12 weeks after the start of use

#### Method of measurement

Trichoscopy By Fotofinder

### 2

#### Description

Changes in percentage of anagen to telogen

#### Timepoint

Before intervention, 6 and 12 weeks the start of use

#### Method of measurement

Trichoscopy By Fotofinder

## Intervention groups

### 1

#### Description

Intervention group: Topical use of Caffeine Plus Irox anti-hair loss serum produced by Iran Avandfar

company(Contains Canadian willow extract, Glycolic extract of green tea, Caffeine , etc..)20 drops once a day, for 12 weeks and topical use of Caffeine Plus Irox anti-hair loss shampoo produced by Iran Avandfar company (Contains sodium lauryl sarcosinate, Cocamidopropyl betaine,Alpha-tocopherol acetate,Caffeine , etc..) at least three times in a week, for 12 weeks.

**Category**

Treatment - Other

**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

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

Iran Avandfar Company

**Full name of responsible person**

Nader Soltani Hoseini

**Street address**

No.80 ,Baquerkhan Ave. ,Sattarkhan St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1441764181

**Phone**

+98 21 6642 2655

**Email**

info@iranbath.com

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

Yes

**Title of funding source**

Iran Avandfar Company

**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

**Position**

Manger of clinical study unit

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Skin Biometrics

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1416613675

**Phone**

+98 21 8896 0880

**Email**

aniseh\_samadi@yahoo.com

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

Tehran University of Medical Sciences

**Full name of responsible person**

Alireza Firooz

**Position**

Professor of dermatology

**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 7921

**Email**

firozali@sina.tums.ac.ir

+98 21 8897 0658

**Email**

ahmadi.maryam648@gmail.com

**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**

Clinical Research

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1416613675

**Phone**

**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