

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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

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