

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluation of safety and the effectiveness of Caffeine Plus Siseh anti-hair loss line (tonic and shampoo) produced by Sina Trading Company In the prevention and treatment of androgenic hair loss

Protocol summary

Study aim

Evaluation of safety and the effectiveness of Caffeine Plus Siseh anti-hair loss line (tonic and shampoo) produced by Sina Trading 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 are taught to use Caffeine liquid Plus Siseh anti-hair loss tonic once a day for 12 weeks and Caffeine Plus Siseh 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.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male aged 18-50 years, 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 tonic and shampoo ingredients, Any severe weight loss or strict diet therapy during the study

Intervention groups

A-Intervention group: Topical use of Caffeine Plus Siseh anti-hair loss serum produced by Sina Trading Company once a day, for 12 weeks. B-Intervention group: Topical use of Caffeine Plus Siseh anti-hair loss shampoo produced by Sina trading company at least three times in 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: **IRCT20161207031288N8**

Registration date: **2021-05-04, 1400/02/14**

Registration timing: **prospective**

Last update: **2021-05-04, 1400/02/14**

Update count: **0**

Registration date

2021-05-04, 1400/02/14

Registrant information

Name

Saman Ahmad Nasrollahi

Name of organization / entity

Center for Research and Training in Skin Diseases and Leprosy Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 8190

Email address

snasrollahi@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 Siseh anti-hair loss line (tonic and shampoo) produced by Sina Trading Company In the prevention and treatment of androgenic hair loss

Public title

Evaluation of safety and the effectiveness of Caffeine Plus Siseh anti-hair loss tonic and shampoo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male aged 18-50 years 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 tonic 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

2021-03-13, 1399/12/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.1256

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 Siseh anti-hair loss serum (Contains 3% prokapol, Ulnalic acid, Biotinyl tripeptide, Caffeine, etc..) produced by Sina Trading Company once a day, for 12 weeks and Topical use of Caffeine liquid Plus Siseh anti-hair loss shampoo (Contains 3% prokapol, Caffeine complex contains vitamin B5 and Zinc PCA) produced by Sina trading company 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.

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1416613675

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+98 21 8897 0658

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dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sina Trading Company

Full name of responsible person

Mehdi Goudarzi

Street address

No. 12, Unit 12, Zayandehrud Alley, North Shiraz St., Mulla Sadra St.

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Sistan-va-Balouchestan

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1991613916

Phone

+98 21 8860 0707

Email

mehdi.goudarzi@sinatco.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sina Trading 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

Saman Ahmad Nasrollahi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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No. 415, Taleghani Ave., Tehran, Iran

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samannasrol@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mansour Nasiri Kashani

Position

Proffesor of Dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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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
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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable