Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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% prokapil, 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% prokapil, 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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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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Chabahar
Province
Sistan-va-Balouchestan
Postal code
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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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Mansour Nasiri Kashani
Position
Proffesor of Dermatology
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Specialist
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Person responsible for updating data

Contact

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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