

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Evaluation of safety and the effectiveness of Scalpia hair strengthening tonic in reducing diffuse and scattered hair loss and Improving hair volume and density

Protocol summary

Study aim

Evaluation of safety and the effectiveness of Scalpia hair strengthening tonic in reducing diffuse and scattered hair loss and Improving hair volume and density

Design

Single group, phase 2, before -after clinical study. sample size is 19.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy, 19 volunteers suffering from diffuse and scattered hair loss will be selected and enrolled in the study after signing consent form. Volunteers will be taught to use Scalpia hair strengthening tonic for 12 weeks once in a day. Before intervention , 6 and 12 weeks after using the product, changing in hair count and hair density will be measured. This study is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male or female aged 18-55 years, Diffuse and scattered hair loss (Count at least 300 hairs in a combing test over three days), General health, 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, Any severe weight loss or strict diet therapy during the study, Pregnancy or breastfeeding

Intervention groups

Intervention group: Topical use of Scalpia hair strengthening tonic (Contains rosemary leaf extract, hops extract, licorice root extract, caffeine, glycerin, panthenol, nettle extract, sodium benzoate, methyl nicotinate, vitamin B6, vitamin B3) produced by Arachemi Pars company, by Spray once in a day, for 12 weeks.

Main outcome variables

Hair count changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N24**

Registration date: **2022-05-18, 1401/02/28**

Registration timing: **prospective**

Last update: **2022-05-18, 1401/02/28**

Update count: **0**

Registration date

2022-05-18, 1401/02/28

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

2022-06-22, 1401/04/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and the effectiveness of Scalpia hair strengthening tonic in reducing diffuse and scattered hair loss and Improving hair volume and density

Public title

Evaluation of Scalpia hair strengthening tonic in reducing hair loss

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female aged 18-55 years Diffuse and scattered hair loss (Count at least 300 hairs in a combing test over three days) General health Voluntary participation and signing written informed consent

Exclusion criteria:

Chronic active scalp disease other than hair loss Using any prescribed drug or Over The Counter(OTC) for hair loss within the past 3 months Any severe weight loss or strict diet therapy during the study Pregnancy or breastfeeding

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **19**

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 in research of medical school-
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

2022-05-07, 1401/02/17

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.107

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 count changes

Timepoint

Before intervention, 6 and 12 weeks after the start of use

Method of measurement

Trichoscopy by Fotofinder

Secondary 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

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 Scalpia hair strengthening tonic (Contains rosemary leaf extract,

hops extract, licorice root extract, caffeine, glycerin, panthenol, nettle extract, sodium benzoate, methyl nicotinate, vitamin B6, vitamin B3) produced by Arachemi Pars company, by Spray once in a day, for 12 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) Street, Taleqani Avenue

City

Tehran

Province

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Postal code

1416613675

Phone

+98 21 8897 0658

Email

dermalab@tums.ac.ir

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

Arachemi Pars company

Full name of responsible person

Gholam Hossein Ardavan Danaei

Street address

Unit 204, second floor, Vanak Passage, Vanak St.

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Tehran

Province

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Postal code

1991945116

Phone

+98 21 8867 0873

Email

info@arachemi.com

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

Yes

Title of funding source

Arachemi Pars 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

Manager of clinical study unit

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

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

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

Tehran University of Medical Sciences

Full name of responsible person

Azin Ayatollahi

Position

Dermatologist

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

Dermatology

Street address

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Postal code

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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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable