

# 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**

Tehran

**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.

**City**

Tehran

**Province**

Tehran

**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**

Manger of clinical study unit

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Dermatology

**Street address**

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

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**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**

Azin Ayatollahi

**Position**

Dermatologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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**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**

Dermatology

**Street address**

خیابان طالقانی، نبش خیابان شهید نادری، شماره ۴۱۵

**City**

Tehran

**Province**

Tehran

**Postal code**

1416613675

**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