

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of safety and effectiveness of Prim anti-dandruff line (anti-dandruff serum and shampoo and dandruff return prevention shampoo), a product of Akhavi Laboratory in the treatment of oily and dry dandruff

Protocol summary

Study aim

Evaluation of safety and effectiveness of Prim anti-dandruff line (anti-dandruff serum and shampoo and dandruff return prevention shampoo), a product of Akhavi Laboratory in the treatment of oily and dry dandruff

Design

The study is a phase 2 before-after clinical trial. The sample size is 28. The study was not randomized.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy in Tehran university of medical sciences, 28 volunteers with oily or dry dandruff of any severity will be selected and enrolled in the study after signing consent form. Volunteers will be taught to use of Prim anti-dandruff line (anti-dandruff serum and shampoo and dandruff return prevention shampoo), a product of Akhavi Laboratory for 16 weeks once in a day. Before intervention ,4, 8 and 16 weeks after using changing in Dandruff severity will be measured. This study is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male and female aged 18-60 years, Good general health, Oily or dry dandruff of any severity, Voluntary participation and sign the written informed consent Exclusion criteria: Chronic active scalp disease other than hair loss, People with allergies to serum and shampoo ingredients, Scalp surgeries

Intervention groups

Intervention group: 8 weeks of using Prim anti-dandruff serum laboratory and dry anti-dandruff shampoo produced by Akhavi as well as 8 weeks of using a mild anti-dandruff shampoo to prevent the return of dandruff

Main outcome variables

Dandruff severity based on the Adherent Scalp Flaking Score (ASFS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150101020514N14**

Registration date: **2021-12-14, 1400/09/23**

Registration timing: **prospective**

Last update: **2021-12-14, 1400/09/23**

Update count: **0**

Registration date

2021-12-14, 1400/09/23

Registrant information

Name

Alireza Firooz

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 8190

Email address

firozali@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and effectiveness of Prim anti-dandruff line (anti-dandruff serum and shampoo and dandruff return prevention shampoo), a product of Akhavi Laboratory in the treatment of oily and dry dandruff

Public title

Evaluation of safety and effectiveness of Prim anti-dandruff line

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male and female aged 18-60 years Good general health Oily or dry dandruff of any severity Voluntary participation and sign the written informed consent

Exclusion criteria:

Chronic active scalp disease other than hair loss People with allergies to serum and shampoo ingredients Scalp surgeries

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **28**

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

Room 105 , 5th floor, Central construction of Tehran University of Medical Sciences, Ghods intersection, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-11-28, 1400/09/07

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.970

Health conditions studied

1

Description of health condition studied

hair Dandruff

ICD-10 code

ICD-10 code description

hair Dandruff

Primary outcomes

1

Description

Dandruff severity based on the Adherent Scalp Flaking Score (ASFS)

Timepoint

Before intervention, 8 and 16 weeks after the start of use

Method of measurement

Dandruff meter

Secondary outcomes

1

Description

Number of dandruff after one minute combing

Timepoint

Before intervention, 4 , 8 and 16 weeks after the start of use

Method of measurement

Dandruff Meter

Intervention groups

1

Description

Intervention group: 8 weeks of using Prim anti-dandruff serum laboratory and dry anti-dandruff shampoo produced by Akhavi as well as 8 weeks of using a mild anti-dandruff shampoo to prevent the return of dandruff

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

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1416613675

Phone

+98 21 8897 0658

Email

dermalab@tums.ac.ir

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

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

Akhavi laboratory

Full name of responsible person

Farid Akhavi

Street address

Unit 8, No.17, Tavanir Street, Valiasr Street

City

Tehran

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Tehran

Postal code

1434875419

Phone

+98 21 8879 8126

Email

info@akhavilab.com

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

Yes

Title of funding source

Akhavi laboratory

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****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

Specialist

Other areas of specialty/work

Dermatology

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firozali@tums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Clinical trial

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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