

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of safety and the effectiveness of Prime (U+) Urea 5% Shampoo, produced by Dr. Akhavi Laboratory in improving of dryness and itching in sensitive scalp

Protocol summary

Study aim

Evaluation of safety and the effectiveness of Prime (U+) Urea 5% Shampoo, produced by Dr. Akhavi Laboratory in improving of dryness and itching in sensitive scalp

Design

Single group, phase 2, before -after clinical study. sample size is 19. 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, 19 volunteers with dryness and itching in scalp will be selected and enrolled in the study after signing consent form. Volunteers will be taught to use Prime (U+) Urea 5% Shampoo produced by Akhavi laboratory for 4 weeks, at least 3 times in a week. Before intervention and 4 weeks after using changing in scalp hydration and severity of itching and burning in scalp will be measured. This study is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male or female aged 18-70 years, General health, Clinical diagnosis of dry scalp, At least grade of 2 out of 10 on itching or scalp irritation, Voluntary participation and signing written informed consent Exclusion criteria: People with allergies to shampoo ingredients, Acute or chronic active disease related to scalp such as psoriasis, Lichen Planus, etc., Any type of malignancy, Pregnancy or breastfeeding

Intervention groups

Topical use of Prime (U+) Urea 5% Shampoo, Dr. Akhavi laboratory product,(Contains disodium coquill glutamate, urea, sodium lactate, chia seed oil, honeysuckle flower extract and etc...) Spray at least 3 times in a week, for 4 weeks

Main outcome variables

Change in scalp hydration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N19**

Registration date: **2022-04-13, 1401/01/24**

Registration timing: **prospective**

Last update: **2022-04-13, 1401/01/24**

Update count: **0**

Registration date

2022-04-13, 1401/01/24

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

2022-04-21, 1401/02/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and the effectiveness of Prime (U+) Urea 5% Shampoo, produced by Dr. Akhavi Laboratory in improving of dryness and itching in sensitive scalp

Public title

Evaluation of safety and the effectiveness of Prime (U+) Urea 5% Shampoo, in improving of dryness and itching in sensitive scalp

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female aged 18-70 years General health Clinical diagnosis of dry scalp At least grade of 2 out of 10 on itching or scalp irritation Voluntary participation and signing written informed consent

Exclusion criteria:

People with allergies to shampoo ingredients Acute or chronic active disease related to scalp such as psoriasis, Lichen Planus, etc. Any type of malignancy Pregnancy or breastfeeding

Age

From **18 years** old to **70 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

2022-01-19, 1400/10/29

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1236

Health conditions studied

1

Description of health condition studied

dryness and itching in sensitive scalp

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Change in scalp hydration

Timepoint

Before intervention and 4 weeks after using

Method of measurement

Corneometry

Secondary outcomes

1

Description

Severity of itching and burning in scalp

Timepoint

Before intervention and 4 weeks after using

Method of measurement

This variable is recorded from 0 to 10 based on the patient's opinion so that 0 is sign of not itching and 10 is sign of maximum itching intensity.

Intervention groups

1

Description

Intervention group: 4 weeks using Prime (U+) Urea 5% Shampoo, Dr. Akhavi laboratory product, at least 3 times in a week

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

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Province

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Postal code

1416613675

Phone

+98 21 8897 0658

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dermalab@tums.ac.ir

Aniseh Samadi

Position

Manger of clinical study unit

Latest degree

Ph.D.

Other areas of specialty/work

Skin Biometrics

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aniseh_samadi@yahoo.com

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

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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****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person**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

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

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

Analytic Code

Not applicable

Data Dictionary

Not applicable