

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation of safety and effectiveness of Eczacin cream made by Pharmed Salamat Sina company in improving mild and moderate atopic dermatitis in adults

Protocol summary

Study aim

Evaluation of safety and effectiveness of Eczacin cream made by Farmed Salamat Sina company in improving mild and moderate atopic dermatitis in adults

Design

It is a phase II interventional study as a non-randomized and before-after clinical study. 19 adult volunteers with atopic dermatitis will participate in the study after signing informed consent.

Settings and conduct

The study will be conducted in Center for Research & Training in Skin Diseases and Leprosy. Participants will receive Eczacin Repairing Cream, twice a day for 4 weeks on affected areas. The assessments of area, by local SCORAD (Severity Scoring of Atopic Dermatitis index) as well as skin biophysical parameters (skin hydration, trans epidermal water loss, erythema, melanin, sebum and Ph) will be performed before intervention, 2 and 4 weeks after treatment. The study is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Chronic or recurrent eczema with a mild to moderate severity and personal or family history of atopia or high IgE level, Signing the consent form for participation in the study, minimum score of one for the SCORAD scale of redness and itching. Exclusion criteria: not to use topical medications for atopic dermatitis (except for moisturizer) in the last 2 weeks or systemic medications in the last 4 weeks, Use of steroids or systemic immunosuppressive drugs with any indication, Pregnancy or lactating, Severe atopic dermatitis (SCORAD above 12)

Intervention groups

Use of Eczacin Repairing Cream made by Pharmed Salamat Sina company twice a day for 4 weeks

Main outcome variables

Local SCORAD (Severity Scoring of Atopic Dermatitis

index) criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210130050179N2**

Registration date: **2021-12-09, 1400/09/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-09, 1400/09/18**

Update count: **0**

Registration date

2021-12-09, 1400/09/18

Registrant information

Name

Taraneh Yazdanparast

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

Email address

drtaraneh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-06, 1400/09/15

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and effectiveness of Eczacin cream made by Pharmed Salamat Sina company in improving mild and moderate atopic dermatitis in adults

Public title

Evaluation of safety and effectiveness of Eczacin cream in improving atopic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Chronic or recurrent eczema with a mild to moderate severity and personal or family history of Atopia or high IgE level Signing the consent form for participation in the study Minimum score of one for the SCORAD (Severity Scoring of Atopic Dermatitis index) scale of redness and itching

Exclusion criteria:

Not to use topical medications for Atopic Dermatitis (except for moisturizer) in the last 2 weeks or systemic medications in the last 4 weeks. Use of steroids or systemic immunosuppressive drugs with any indication. Pregnancy or lactating Severe atopic dermatitis (SCORAD above 12)

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **19**

Randomization (investigator's opinion)

Not randomized

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 Street, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-11-16, 1400/08/25

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.926

Health conditions studied**1****Description of health condition studied**

Atopic dermatitis

ICD-10 code

L20

ICD-10 code description

Atopic dermatitis

Primary outcomes**1****Description**

Local SCORAD (Severity Scoring of Atopic Dermatitis index) criteria

Timepoint

Before intervention and 2 and 4 weeks after treatment

Method of measurement

Research physician will perform clinical assessments according to the local SCORAD (Severity Scoring of Atopic Dermatitis index) grade

Secondary outcomes**1****Description**

Trans epidermal water loss

Timepoint

Before intervention and 2 and 4 weeks after treatment

Method of measurement

Tewameter

2**Description**

stratum corneum hydration

Timepoint

Before intervention and 2 and 4 weeks after treatment

Method of measurement

Corneometer

Intervention groups

1

Description

Intervention group: Use Eczacin Repairing Cream product by Sina pharmed salamat twice a day for 4 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

Taraneh Yazdanparast

Street address

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

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Email

drtaraneh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sina pharmed salamat

Full name of responsible person

Elahe Valinejad

Street address

No. 110, Sheikh Baha'i St. South, Mulla Sadra Street, Vanak Square

City

Tehran

Province

Tehran

Postal code

1435916565

Phone

+98 21 8619 4465

Email

hi@pharmedsalamatco.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sina pharmed salamat

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

Taraneh Yazdanparast

Position

Research Physician

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

Street address

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

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8896 0880

Email

drtaraneh@yahoo.com

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 7921

Email

firozali@sina.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

Research Expert

Latest degree

Master

Other areas of specialty/work

Clinical Research

Street address

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

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 0658

Email

ahmadi.maryam648@gmail.com

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