

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical study of topical nanoliposome formulation of ruxolitinib 1.5% in treatment of mild to moderate atopic dermatitis

Protocol summary

Study aim

Evaluation of clinical efficacy of topical formulation of ruxolitinib 1.5% in treatment of atopic dermatitis

Design

Phase II single group, before -after

Settings and conduct

This clinical and interventional before-after study is performed in Center for Research and Training in Skin Diseases and Leprosy, Tehran University of Medical Sciences. 20 patients with dermatitis atopic who want to participate in the study and complete the consent form are entered in the study. They receive topical emulgel ruxolitinib 1.5% twice daily for 4 weeks and the rate of healing is evaluated 2 and 4 weeks after treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Case of mild to moderate atopic dermatitis
Exclusion criteria: Pregnancy and lactation and sever atopic dermatitis

Intervention groups

Intervention group: Topical use of emulgel of nanoliposomes contain ruxolitinib 1.5 percent produced by lipid film hydration method in the faculty of pharmacy of Tehran university of medical sciences twice a day and for 4 weeks

Main outcome variables

severity of lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161207031288N9**

Registration date: **2021-06-01, 1400/03/11**

Registration timing: **prospective**

Last update: **2021-06-01, 1400/03/11**

Update count: **0**

Registration date

2021-06-01, 1400/03/11

Registrant information

Name

Saman Ahmad Nasrollahi

Name of organization / entity

Center for Research and Training in Skin Diseases and Leprosy Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 8190

Email address

snasrollahi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-10, 1400/03/20

Expected recruitment end date

2021-12-11, 1400/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical study of topical nanoliposome formulation of ruxolitinib 1.5% in treatment of mild to moderate atopic dermatitis

Public title

Clinical study of topical nanoliposome formulation of ruxolitinib 1.5% in treatment of eczema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Case of mild to moderate atopic dermatitis (SCORAD between 4 and 12) Older than 18 years Signing informed consent to participate in the study Having a negative pregnancy test Willingness to actively participate in the study

Exclusion criteria:

Pregnancy and lactation Use of any topical corticosteroids in the last 14 days Drug and alcohol addiction Use of oral corticosteroids or other immunosuppressive drugs in the last 28 days

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

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**

Tehran University Of Medical Sciences(TUMS)

Street address

Taleghani and Naderi intersection-Center for Research and Training of Skin Disease and Leprosy

City

Tehran

Province

Tehran

Postal code

1416613675

Approval date

2019-02-17, 1397/11/28

Ethics committee reference number

IR.TUMS.TIPS.REC.1397.142

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**

severity of lesions of atopic dermatitis according to Scord score

Timepoint

Before intervention, and 2 and 4 weeks after than

Method of measurement

Clinical exam

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

Dermal erythema variations

Timepoint

Before intervention, and 2 and 4 weeks after than

Method of measurement

Mexameter

Intervention groups**1****Description**

Intervention group: Topical use of emulgel of nanoliposomes contain ruxolitinib 1.5 percent produced by lipid film hydration method in the faculty of pharmacy of Tehran university of medical sciences twice a day and 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

Dr. Alireza Firooz

Street address

Taleghani-Naderi intersection

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+98 21 8899 3305

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dermalab@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Mohammadreza Rouini

Street address

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pharmacy@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Centre for Research and Training in Skin Diseases and Leprosy

Full name of responsible person

Dr. Alireza Firooz

Position

Dermatologist, Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Centre for Research and Training in Skin Diseases and Leprosy

Full name of responsible person

Dr. Alireza Firooz

Position

Dermatologist, Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Atefeh Naeimifar

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable