

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

A clinical trial to evaluate the effect of topical liposomal formulation of *Althaea officinalis* and compare it with topical hydrocortisone acetate (1%) ointment in improving and control symptom in patients with atopic eczema

Protocol summary

Summary

The aim of this study is comparing the effect of liposomal formulations containing the *Althaea officinalis* extract with 1% hydrocortisone cream to relieve the symptoms of atopic dermatitis. In this study all of patients have criteria atopic dermatitis and the exclusion criteria are include sensitivity to the new formulation, simultaneous existence another skin disease or used of systemic immunosuppressive medications. Study are done in 20 patients ranging in age from 10 to 40 years with confirmed clinical criteria by allergist. After consent from the patient, in the double-blind form they receive liposomal formulations of *Althaea officinalis* extract and placebo for a month simultaneously in packages. Patient use these packets the on half of the body lesion and taking hydrocortisone 1% on the other half of the body lesion during per month. Based on questionnaire every two weeks (two times in each month) the effect of formulations (drug or placebo) with 1% hydrocortisone cream will compare to measure symptoms relieve (tingling, itching, redness, bumps, scaling and fissures)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102323235N5**
Registration date: **2016-12-21, 1395/10/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-21, 1395/10/01

Registrant information

Name

Farahzad Jabbari Azad

Name of organization / entity

Allergy Research Center, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-04-13, 1395/01/25

Expected recruitment end date

2017-04-14, 1396/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to evaluate the effect of topical liposomal formulation of *Althaea officinalis* and compare it with topical hydrocortisone acetate (1%) ointment in improving and control symptom in patients with atopic eczema

Public title

The impact of *Althaea officinalis* formulation on controlling the symptoms of atopic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Confirm eczema atopic dermatitis by an allergist according to plan; family history of atopy; positive allergy tests (skin prick test) ; Complete the consent form Exclusion criteria Local sensitivity to new formulations; Patients with diseases of the skin; Systemic immunosuppressive drugs; Lack of cooperation during treatment; waste infections that require antibiotics or drug penetration increase; patients with atopic eczema lesions with high emissions (over 50%) of body surface

Age

From **10 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mashahd University of Medical Science

Street address

Azadi square

City

Mashhad

Postal code**Approval date**

2016-04-13, 1395/01/25

Ethics committee reference number

IR.MUMS.fm.REC.1394.543

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

Atopic Eczema

ICD-10 code

L20.8

ICD-10 code description

Other atopic dermatitis

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

The severity of the itch

Timepoint

monthly

Method of measurement

questionnaire

2**Description**

inflammation

Timepoint

monthly

Method of measurement

questionnaire

3**Description**

The size of the lesion

Timepoint

monthly

Method of measurement

questionnaire

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

The severity of the itch

Timepoint

monthly

Method of measurement

questionnaire

2**Description**

The inflammation

Timepoint

monthly

Method of measurement

questionnaire

3**Description**

The size of the lesion

Timepoint

monthly

Method of measurement

questionnaire

Intervention groups

1

Description

in Control groups, the liposomal placebo in half of the body (right) and in the second half (left) of hydrocortisone ointment is used locally for a month

Category

Placebo

2

Description

in the Intervention group, the Althaea officinalis liposomal in half of the body (right) and in the second half (left) of the body hydrocortisone ointment is used locally for a month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Mommamad Mohammadzadeh Shabestari

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

university street

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Science

Full name of responsible person

Mommamad Mohammadzadeh Shabestari

Position

General Medicine Students

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Science

Full name of responsible person

Farzaneh Iravani

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MSc of human genetics

Other areas of specialty/work

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farzaneh.baroon@gmail.com

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty