

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Evaluating the effect of topical mirtazapine on management of pruritus in patient with eczema

Protocol summary

Summary

This study is a randomized, placebo-controlled, double-blind trial in 120 patients with atopic dermatitis aged 18 years to 65 years with poor response to conventional treatment (topical steroids and oral antihistamines) at dermatology clinic of Afzalipour hospital in Hamadan. After confirmation of atopic dermatitis by dermatologist and the same drug prescription, all Patients will be randomly allocated into two groups according to Random number tables. Intervention group will receive topical mirtazapine 5% four times a day for 10 days with topical betamethason and control group will receive topical betamethason without mirtazapine. Severity of clinical symptoms and pruritus determine by visual analogue scale at baseline, 5 days and 10 days after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071722965N3**

Registration date: **2015-11-04, 1394/08/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-04, 1394/08/13

Registrant information

Name

Maryam Mehrpooya

Name of organization / entity

School of Pharmacy, Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3821 8684

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamadan University of Medical Sciences

Expected recruitment start date

2015-09-01, 1394/06/10

Expected recruitment end date

2016-09-01, 1395/06/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of topical mirtazapine on management of pruritus in patient with eczema

Public title

Effect of topical mirtazapine on eczema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18-65 years old; Moderate to severe eczema; Patients who less than 25% of their skin is involved; Discontinue of glucocorticoid agents 4 weeks prior to the investigation; Discontinue of anti pruritis agents 1 week prior to the investigation
Exclusion criteria: Age less than 18 years old; Patients with inflammatory skin disease; Pregnant woman

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **120****Randomization (investigator's opinion)**

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Neither the participants or the experimenters know who is receiving a particular treatment

Secondary Ids

empty

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Khajerashid, Ayatollah kashani, Hamadan University of Medical Sciences

City

Hamadan

Postal code**Approval date**

2015-05-20, 1394/02/30

Ethics committee reference number

IR.UMSHA.REC.1394.233

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

Atopic dermatitis

ICD-10 code

L20.8

ICD-10 code description

Other atopic dermatitis

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

Eczema

Timepoint

5 and 10 days following of treatment

Method of measurement

Visual Analogue Score

Secondary outcomes

empty

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

Intervention group: Betamethason cream plus mitazapine 5% cream 4 times per day for 10 days

Category

Treatment - Drugs

2**Description**

Control group: Betamethason cream plus placebo mitazapine 5% cream 4 times per day for 10 days

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Khomeini Hospital

Full name of responsible person

Alireza Ahmadi

Street address

Mirzadeh Eshghi Ave, Emam Khomeini Hospital, Hamadan

City

Hamadan

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

Vice chancellor for research, Hamadan University of Medical Sciences

Full name of responsible person

Alireza Ahmadi

Street address

Hamedan University of Medical Sciences, Shahid Fahmide avenue, Hamedan

City

Hamadan

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, Hamadan 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

Person responsible for scientific inquiries

Contact

Name of organization / entity
School of Pharmacy, Hamadan University of Medical Sciences
Full name of responsible person
Maryam Mehrpooya
Position
Assistant Professor
Other areas of specialty/work
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Web page address

Person responsible for updating data

Contact

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