Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effect of topical Atorvastatin as adjuvant therapy in treatment of hand eczema

Protocol summary

Summary

This study is a randomized, placebo-controlled, double-blind trial in 70 patients with dermatitis aged 18 years to 65 years with poor response to conventional treatment (topical steroids) at dermatology clinic of Sina hospital in Hamadan. After confirmation of 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 atorvastatin 5% two times a day for 10 days with topical betamethason and control group will receive topical betamethason without atorvastatin. Severity of clinical symptoms and pruritus determine by Hand eczema index at baseline, 5 days and 10 days after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070922965N10**
Registration date: **2017-07-18, 1396/04/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-07-18, 1396/04/27

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamadan University of Medical Sciences

Expected recruitment start date

2017-08-19, 1396/05/28

Expected recruitment end date

2018-08-19, 1397/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of topical Atorvastatin as adjuvant therapy in treatment of hand eczema

Public title

Effect of topical Atorvastatin on hand 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; Discountinue of glucocorticoid agents 4 weeks prior to the investigation; Discountinue of antipuritis 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: **70**
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
2017-06-24, 1396/04/03
Ethics committee reference number
IR.UMSHA.REC.1396.290

Health conditions studied

1

Description of health condition studied
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
Hand eczema index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Betamethason ointment plus atorvastatin 5% cream 2 times per day for 10 days
Category
Treatment - Drugs

2

Description
Control group: Betamethason ointment plus placebo atorvastatin 5% cream 2 times per day for 10 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Street address
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
Hamedan
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

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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