

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

evaluating of clobetasol 0.05% and doxepine 5% cream vs clobetasol 0.05% and placebo in the treatment of moderate to severe hand eczema

Protocol summary

Summary

In this randomized double blind clinical trial 70 patients with moderate to severe hand eczema entered our study considering inclusion and exclusion criteria and randomly divide in two groups. Inclusion criteria: all patients with moderate to severe hand eczema that are 12 to 70 years old exclusion criteria: treatment with systemic steroid less than 1 month before trial; treatment with topical steroid and antihistamines at the time of presentation ;pregnancy;lactation;age less than 12.one group receive topical steroid and doxepine 5% cream and the other use topical steroid and placebo twice a day for 8 days. Patients data such as demographic features, severity of clinical symptoms and pruritus collect by questionnaire. Hand eczema severity index and visual analogue scale are our criterion for determination of clinical symptoms and pruritus severity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112018263N1**

Registration date: **2012-05-05, 1391/02/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-05-05, 1391/02/16

Registrant information

Name

Farideh Dehghani

Name of organization / entity

Shahid Sadooghi University of Medical Sciences, Yazd

Country

Iran (Islamic Republic of)

Phone

+98 35 1525 0093

Email address

farideh.dehghan@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadooghi university of Medical Sciences, Yazd

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2012-08-20, 1391/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluating of clobetasol 0.05% and doxepine 5% cream vs clobetasol 0.05% and placebo in the treatment of moderate to severe hand eczema

Public title

evaluating of clobetasol 0.05% and doxepine 5% cream vs clobetasol 0.05% and placebo in the treatment of moderate to severe hand eczema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients with moderate to severe hand eczema that are 12 to 70 years old exclusion criteria: treatment with systemic steroid less than 1 month before trial; treatment with topical steroid and antihistamines at the time of presentation ;pregnancy;lactation;age less than 12

Age

From **12 years** old to **70 years** old

Gender

Both

Phase
1

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Şahid Sadooghi University of Medical Sciences,Yazd

Street address
central office of Şahid Sadooghi University of
Medical Sciences, Shahid Sadooghi blv,Yazd

City
Yazd

Postal code

Approval date
2012-02-27, 1390/12/08

Ethics committee reference number
153947/1/17/پ

Health conditions studied

1

Description of health condition studied
hand eczema

ICD-10 code
L20.8

ICD-10 code description
Other atopic dermatitis

Primary outcomes

1

Description
reduction or improvement of hand eczema

Timepoint
before and 8 days after treatment

Method of measurement

hand eczema severity index

Secondary outcomes

1

Description
adverse effects

Timepoint
8 days after initiation of treatment

Method of measurement
8 days after initiation of treatment

Intervention groups

1

Description
doxepine 5% cream and clobetasol 0.05% are applied
twice a day for 8 days

Category
Treatment - Drugs

2

Description
clobetasol 0.05% and placebo are applied twice a day for
8 days

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Poly Clinic and subspecialty Khatamolanbia

Full name of responsible person
Farideh Dehghani, MD

Street address
Taleghani blv, Yazd

City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Şahid Sadooghi University of Medical Sciences,Yazd

Full name of responsible person
Fatemeh Ezoddini, MD

Street address
central office of Şahid Sadooghi university of Medical
Sciences, Shahid Sadooghi blv,Yazd

City
Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadooghi University of Medical Sciences,Yazd

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

Shahid Sadooghi University of Medical Sciences,Yazd

Full name of responsible person

Farideh Dehghani, MD

Position

Assistant professor of dermatology

Other areas of specialty/work

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Web page address

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