

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating of Anti-dry cream vs Flucinolone acetonide 0/o25% cream in treatment of hand eczema

Protocol summary

Summary

Major objectives: Effect of Anti-dry cream (contains essences of Lavender, Geranium, and Aloe vera) on improving manifestations of hand eczema in comparison with Fluocinolone acetonide 0.025% cream. Design: Randomized controlled double-blinded study. Setting and conduct: 108 eligible patients with hand eczema attending to dermatologic clinic will be enrolled in this study after filling consent form and randomized into two groups (control and intervention group). Inclusion criteria: Patients with hand eczema that is confirmed by dermatologist; age between 18-75 y/o; patients should be eager to participate in trial. Exclusion criteria: Pregnancy and lactation; application of topical drugs during previous two weeks; systemic therapies such as corticosteroids, and antibiotics during the past 4 weeks; localized hand infection; history of allergic reaction to the study medications. Intervention: Anti-dry cream and Fluocinolone acetonide 0.025% will be prepared in the identical tubes which only labeled by numbers. Participants will apply maximally one gram of medications topically on eczematous lesions twice a day for a period of two weeks; the amount of applied creams is estimated by Finger Tip Unit (FTU). Main outcome: Patients will be assessed at 2 determined time points: at first attending session and two weeks after initiating treatment. A Questionnaire (contains of clinical signs and symptoms: erythema, scaling, lichenification/ hyperkeratosis, edema, vesicle, fissure, pruritus and pain) will be filled out by dermatologist in the days of 0 and 14. The Hand Eczema Severity Index will be used to assess the extent, severity and improvement of the disease during each session.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212303734N2**

Registration date: **2013-08-30, 1392/06/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-30, 1392/06/08

Registrant information

Name

Rezvan Talaee

Name of organization / entity

Kashan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1445 5370

Email address

talaei-re@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan university of medical sciences, Barij essence herbal medicine research center

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating of Anti-dry cream vs Flucinolone acetonide 0/o25% cream in treatment of hand eczema

Public title

Efficacy of Anti-dry cream in treatment of hand eczema

Purpose

Treatment

Inclusion/Exclusion criteria

Main inclusion criteria: age between 18-75y/o; patients should be eager to participate in trial; patients with hand eczema that is confirmed by dermatologist. Main exclusion criteria: pregnancy and lactation; application of topical drugs during previous two weeks; systemic therapies such as corticosteroids, immunosuppressive drugs and antibiotics during the past 4 weeks; localized hand infection; history of allergic reaction to the study medications.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kashan university of medical sciences

Street address

5th kilometer of Ghotb Ravandi Bulvard

City

Kashan

Postal code

87159/88141

Approval date

2011-08-09, 1390/05/18

Ethics committee reference number

29/5/1/1392/ب

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

Hand eczema

ICD-10 code

ICD-10: L3

ICD-10 code description

ICD-10: Dermatitis unspecified Eczema NOS

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

Change of signs and symptoms of hand eczema

Timepoint

The days of 0 and 14

Method of measurement

Questionnaire (contains of clinical signs and symptoms: erythema, scaling, lichenification/ hyperkeratosis, edema, vesicle, fissure, pruritus and pain)

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

Side effects of drugs

Timepoint

14 days after prescription of drug

Method of measurement

Change of pruritus, erythema and scaling, bullae

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

Intervention group: Anti dry® cream (contains Aleo vera essence, Geranium essence, Lavander essence, respectively, with ratio of 50:1:15 in vanishing cream), 1FTU (finger tip unit= 0.5g) for 10×10 cm², twice daily, for two weeks.

Category

Treatment - Drugs

2**Description**

control group: fluocinolon acetone cream 0.025%, twice daily, for two weeks

Category

Treatment - Drugs

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

Dermatology clinic of Beheshti hospital

Full name of responsible person

Rezvan Talaei
Street address
Beheshti hospital, 5th kilometer of Ghotbravandi Bul.
City
Kashan

empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Barij Essence Herbal Medicine Research Center
Full name of responsible person
Dr. Reza Bekhradi
Street address
Po Box 1178, Mashhad Ardehal
City
kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Barij Essence Herbal Medicine Research Center
Proportion provided by this source
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

2

Sponsor

Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Dr. Gholam Ali Hamidi
Street address
Kashan university of medical sciences, 5th Kilometer of Ghotb Ravandi Bulvard
City
Kashan
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, Kashan University of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin

Person responsible for general inquiries

Contact

Name of organization / entity
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Rezvan Talaei
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Assistant professor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position

Assistant professor

Other areas of specialty/work**Street address**

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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