

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluating of Anti-dry cream vs Flucinolone acetone 0.025% 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 acetone 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 acetone 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

talaee-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 acetone 0.025% 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 Bulvar

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 Talaee

Street address

Beheshti hospital, 5th kilometer of Ghotbravandi Bul.

City

Kashan

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 Bulvar

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

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

Kashan university of medical sciences

Full name of responsible person

Rezvan Talaee

Position

Assistant professor

Other areas of specialty/work

Street address

Dermatology department of Beheshti hospital, 5th kilometer of Ghotb Ravandi Bulvar

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Person responsible for scientific inquiries

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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