Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, immunosupressive 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 committe 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 acetonide 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 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

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 Bulvard

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Person responsible for scientific inquiries

Contact

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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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Full name of responsible person
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Position
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Other areas of specialty/work

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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