Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Sep 2023

The evaluation of efficacy of topical use of Nigella cream (Nigella sativa oil-extract) in comparison with topical use of 0.1% Betamethasone and Eucerin on the clinical severity and quality of life in patients with chonic hand eczema reffering to Loghman-e-Hakim and Shohada-e-Tajrish hospitals during the year 1388-1389

Protocol summary

Summary

Aim: This randomized controlled patient-blinded pilot study is designed to show the effect of nigella cream on improving quality of life and severity of hand eczema in contrast to betamethasone and eucerin cream. Inclusion criteria: hand eczema due to either occupational dermatitis, atopic dermatitis, or irritant dermatitis of the hands (bilateral or unilateral) Exclusion criteria: pregnancy, lactation, history of allergic reaction to the study medications, local infection in the site of eczema Study population: Sixty eligible patients of dermatologic clinics of Loghman and Shohada-e-Tajrish hospitals will be enrolled in the study. Intervention: The nigella cream with eucerin base is made by a valid pharmacology company. For blinding the participants but not investigators, all three creams(Nigella, Betamethasone, eucerin as placebo) will be prepared in the identical tubes which only labeled A, B, and C with no other information. Participants will apply maximally one gram of study drugs topically on eczematous lesions twice a day for a period of four weeks; the amount of applied creams is estimated by Finger Tip Unit (FTU). Duration of the study: during January 2010 to March 2012 Primary outcome: Patients will be assessed at 3 determined time points: at first attending session, at weeks two and four after initiating treatment. The Hand Eczema Severity Index (HECSI) will be used to assess the extent, severity and improvement of the disease during each session. Farsi version of Dermatologic Life Quality Index (DLQI) that its validity and reliability in assessing vitiligo is confirmed previously will be used too.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111266959N3**
Registration date: **2012-01-11, 1390/10/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-01-11, 1390/10/21

Registrant information

Name

Behrooz Barikbin

Name of organization / entity

skin research center, shohada tajrish hospital, tehran, iran.

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Skin research center of Shahid Beheshti medical universiy

Expected recruitment start date

2010-01-01, 1388/10/11

Expected recruitment end date

2012-03-31, 1391/01/12

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The evaluation of efficacy of topical use of Nigella cream (Nigella sativa oil-extract) in comparison with topical use of 0.1% Betamethasone and Eucerin on the clinical severity and quality of life in patients with chonic hand eczema reffering to Loghman-e-Hakim and Shohada-e-Tajrish hospitals during the year 1388-1389

Public title
The evaluation of efficacy of topical use of Nigella cream (Nigella sativa oil-extract) in chonic hand eczema
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: - age between 18-60 y/o - patients should be eager to participate in trial -patients should have chronic hand eczema that is confirmed by two dermatologist separetely Exclusion criteria: -pregnancy and lactation -application of topical drugs during previous two weeks -usage of systemic therapies such as corticosteroids and immunosupressive drugs and antibiotics during the past 4 weeks - localized hand infection -history of hand contact dermatitis due to topical drugs including herbal remedies
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti university of medical sciences
Street address
Shahid beheshti medical university, Velenjak
City
Tehran
Postal code
Approval date
2009-12-29, 1388/10/08
Ethics committee reference number
88/814 پ/ ت/م

Health conditions studied

1

Description of health condition studied
hand eczema
ICD-10 code
L30.9
ICD-10 code description
Dermatitis, unspecified Eczema NOS

Primary outcomes

1

Description
quality of life
Timepoint
2 weeks
Method of measurement
Dermatology Life Quality Index (DLQI)

2

Description
resolution of severity and intensity of lesions
Timepoint
2 weeks
Method of measurement
Hand Eczema Severity Index (HECSI)

Secondary outcomes

1

Description
Irritant or allergic contact dermatitis
Timepoint
4 weeks
Method of measurement
physician assessment

Intervention groups

1

Description
The nigella cream with eucerin base is made by a valid

pharmacology company. For blinding the participants but not investigators, all three creams(Nigella, Betamethasone, eucerin as placebo) will be prepared in the identical tubes which only labeled A, B, and C with no other information. Intervention group Participants will apply maximally one gram of study drugs topically on eczematous lesions twice a day for a period of four weeks; the amount of applied creams is estimated by Finger Tip Unit (FTU).

Category

Treatment - Drugs

2

Description

We use Eucerin as a creamy base for the nigella oil so we use eucerin as a placebo. The Eucerin cream will be prepared in tubes with the same weight and appearance to nigella cream tubes and randomly will be administered for the patients. In this group the eucerin cream is applied twice daily for 4 weeks in amount of a finger tip units and the maximum dose is 1 gr per each application.

Category

Placebo

3

Description

We use Eucerin as a creamy base for the nigella oil so we use eucerin as a base for betamethasone cream too. The betamethasone cream will be prepared in tubes with the same weight and appearance to nigella and placebo cream tubes and randomly will be administered for the patients. In this group the betamethasone cream is applied twice daily for 4 weeks in amount of a finger tip units and the maximum dose is 1 gr per each application.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology department of Loghman e Hakim hospital

Full name of responsible person

Behrooz Barikbin

Street address

Loghman e Hakim hospital, Makhsus st, Charrah e Lashkar, Karegar st

City

Tehran

2

Recruitment center

Name of recruitment center

Dermatology department of Shohada e Tajrish hospital

Full name of responsible person

Maryam Usefi

Street address

Shohada e Tajrish hospital, Tajrish sq

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Skin research center of Shahid Beheshti university of medical sciences

Full name of responsible person

Parviz Tousi

Street address

Shohada e Tajrish hospital, Tajrish Sq

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Skin research center of Shahid Beheshti 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

Contact

Name of organization / entity

Skin research center of Shahid Beheshti university of medical sciences

Full name of responsible person

Behrooz Barikbin

Position

professor assistant

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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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