

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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 chronic hand eczema referring 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

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Recruitment status

Recruitment complete

Funding source

Skin research center of Shahid Beheshti medical university

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 chronic hand eczema referring 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 chronic 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 separately Exclusion criteria: -pregnancy and lactation -application of topical drugs during previous two weeks -usage of systemic therapies such as corticosteroids and immunosuppressive 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

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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

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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

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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**Street address**

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Person responsible for scientific inquiries

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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