

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effect of anise oil cream 7% in treatment of patients with eczema: a randomized controlled clinical trial

Protocol summary

Study aim

Determination of the efficacy of of anise oil cream 7% in treatment of patients with eczema

Design

Two arm parallel group randomized clinical trial, double blinded

Settings and conduct

Samples include the patients with hand eczema who refer to the Shahid Faghih Dermatology Clinic. In order to blind the investigator, medications are named as "A" for cream of anise oil and B for triamcinolone ointment. The patients were not aware of which drug they received. In addition, the groups are entered into statistical analysis as "A" and "B".

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patient with chronic eczema of hand 2. Age between 18-60 years old 3. Patient Satisfaction to participate in the research project*** Exclusion criteria: 1. Pregnant and lactating women 2. Patients with infectious eczema 3. Use of topical medication in the last two weeks 4. Use of systemic steroids or other oral medication that for treatment the eczema in the last month 5. Positive history of allergy to herbal medicines 6. Patients with autoimmune diseases 7. Patients with hyper sensitivity disorders 8. Patients with other dermatology disorders 9. Patients with rheumatology disorders

Intervention groups

Group A: Use of topical product of anise twice daily for one month*** Group B: Use of topical triamcinolone twice daily for one month

Main outcome variables

Severity of hand eczema

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150825023753N10**

Registration date: **2018-10-07, 1397/07/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-07, 1397/07/15**

Update count: **0**

Registration date

2018-10-07, 1397/07/15

Registrant information

Name

Mohammad Mahdi Parvizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3212 5592

Email address

parvizim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-07, 1397/07/15

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of anise oil cream 7% in treatment of patients with eczema: a randomized controlled clinical trial

Public title

Evaluation of the effect of anise oil cream 7% in treatment of patients with eczema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with chronic eczema of hand Age between 18-60 years old Patient Satisfaction to participate in the research project

Exclusion criteria:

Pregnant and lactating women Patients with infectious eczema Use of topical medication in the last two weeks Use of systemic steroids or other Oral medication that for treatment the eczema in the last month History of allergy to herbal medicines Patients with autoimmune diseases Patients with hyper sensitivity disorders Patients with other dermatology disorders Patients with rheumatology disorders

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation software Ink was used to create a randomization table

Blinding (investigator's opinion)

Triple blinded

Blinding description

In order to blind the investigator, medications were named A (anise cream) and B (triamcinolone). The patients were not aware of which drug they received. The groups were also coded A and B to the statistical analyzer.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Medical School of Shiraz University of Medical Sciences

Street address

Medical School of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2018-08-07, 1397/05/16

Ethics committee reference number

IR.SUMS.MED.REC.1397.205

Health conditions studied

1

Description of health condition studied

Eczema

ICD-10 code

L23.9

ICD-10 code description

Allergic contact dermatitis, unspecified cause

Primary outcomes

1

Description

Severity of eczema

Timepoint

Assessment the severity of eczema at the start of the study, one month after beginning the treatment, and one month after discontinue the treatment

Method of measurement

Use of Eczema Area and Severity Index (EASI score)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Use of topical product of anise twice daily for one month

Category

Treatment - Drugs

2

Description

Control group: Use of topical triamcinolone twice daily for one month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi Dermatology Clinic

Full name of responsible person

Dr. Nasrin Saki

Street address

Shahid Faghihi Hospital, Zand Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mehdi Pasalar

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic data and the result of the clinical trial

When the data will become available and for how long

6 month later

To whom data/document is available

Researchers

Under which criteria data/document could be used

After publication of the extracted article of the clinical trial

From where data/document is obtainable

Sending Email to the researchers

What processes are involved for a request to access data/document

Sending the request via the email

Comments