

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of triamcinolone 0.1% topical cream with Timolol 0.5% topical cream in the treatment of patients with hand or foot eczema

Protocol summary

Study aim

Comparison of the effect of triamcinolone 1.0% topical cream with timolol 0.5% cream in the treatment of patients with hand and/or foot eczema.

Design

A clinical trial with a control group, parallel groups, double-blind, randomized, phase 3 on 32 patients (64 body part/samples). Sealed envelope will be used for randomization.

Settings and conduct

The study is being conducted on a group of 32 patients with eczema visiting the dermatology clinics of Alzahra and Sadegheh Tahereh hospitals. The study is a clinical trial. Triamcinolone 1% cream is used on one hand or foot, and timolol 0.5% cream is used on the opposite hand or foot in this study. After 4 weeks, patients are visited for treatment evaluation, and they are visited again for re-evaluation after another 4 weeks. Patients are scored based on the modified total lesion symptom score (mTTLSS). The type of treatment is determined by the pharmacist, and patients and doctors are not aware of the treatment type.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients presenting to the Alzahra and Sadeghieh skin clinics with complaints of hand or foot eczema. Exclusion criteria: Pregnancy; lactation; cardiac arrhythmias; hypertension; syncope history

Intervention groups

Intervention group 1: puts triamcinolone cream on the right hand or foot and timolol cream on the left hand or foot. Intervention group 2: they put triamcinolone cream on the left hand or foot and timolol cream on the right hand or foot.

Main outcome variables

modified Total Lesion Symptom Score(mTLSS) Score
1:mild Score2:moderate Score3:severe

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150706023081N3**

Registration date: **2024-03-04, 1402/12/14**

Registration timing: **prospective**

Last update: **2024-03-04, 1402/12/14**

Update count: **0**

Registration date

2024-03-04, 1402/12/14

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

iraji@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-25, 1403/01/06

Expected recruitment end date

2026-01-24, 1404/11/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of triamcinolone 0.1% topical

cream with Timolol 0.5% topical cream in the treatment of patients with hand or foot eczema		Assignment Parallel
Public title The effect of Timolol cream in the treatment of eczema		Other design features
Purpose Treatment		Secondary Ids empty
Inclusion/Exclusion criteria Inclusion criteria: Patients referred to Alzahra and Sediqah Tahereh skin clinic Presence of hand or foot eczema complication Exclusion criteria: Cardiac arrhythmia disorders Hypertension History of syncope Pregnancy Breastfeeding		Ethics committees 1 Ethics committee Name of ethics committee Isfahan university of medical sciences Street address Hezarjerib City Isfahan Province Isfahan Postal code 8174673461 Approval date 2023-12-24, 1402/10/03 Ethics committee reference number IR.MUI.MED.REC.1402.356
Age No age limit		
Gender Both		
Phase 3		
Groups that have been masked - Participant - Care provider		
Sample size Target sample size: 32 More than 1 sample in each individual Number of samples in each individual: 2 One group applies triamcinolone cream to the right hand or foot and timolol cream to the left hand or foot, while the other group applies triamcinolone cream to the left hand or foot and timolol cream to the right hand or foot.		Health conditions studied 1 Description of health condition studied eczema ICD-10 code L20.9 ICD-10 code description Atopic dermatitis, unspecified
Randomization (investigator's opinion) Randomized		
Randomization description Using sealed envelope technique, patients will be randomly divided into 2 groups of 32 patients treated with triamcinolone in the right hand or foot and timolol in the left hand or foot in one group and treated with triamcinolone in the left hand or foot and timolol in the right hand or foot in the other group. There will be 32 envelopes, 16 of which will the letter "a" been written on them and the other 16 have the letter "b" written on them. For each patient who enters the study, we will randomly pick one of the envelopes and the patient will be placed in that group. The kind of treatment in group a and group b will be determined by the pharmacist so that the researcher won't be aware of the treatment for each group.		Primary outcomes 1 Description modified Total Lesion Symptom Score(mTLSS) Timepoint At the beginning of the study and 4 weeks and 8 weeks after the start of treatment Method of measurement Taking pictures and measuring the modified Total Lesion Symptom Score
Blinding (investigator's opinion) Double blinded		
Blinding description One group applies triamcinolone cream to the right hand or foot and timolol cream to the left hand or foot, while the other group applies triamcinolone cream to the left hand or foot and timolol cream to the right hand or foot. The doctor and the patient are unaware of this, and it is the responsibility of the pharmacist to determine which group is group one and which group is group two.Both topical cream models have similar packaging		Secondary outcomes empty
Placebo Not used		Intervention groups 1 Description Intervention group 1:Triamcinolone cream 0.1% is

applied to the right hand or foot once a day for 4 weeks and timolol 0.5% cream is applied to the left hand or foot once a day for 4 weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: Triamcinolone cream 0.1% is applied to the left hand or foot once a day for 4 weeks and timolol 0.5% cream is applied to the right hand or foot once a day for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Mehrdad Noroozi

Street address

Hezarjarib

City

Isfahan

Province

Isfahan

Postal code

7573181746

Phone

+98 31 3822 0000

Email

Alzahra@mui.ac.ir

2

Recruitment center

Name of recruitment center

Sadeghieh Tahereh Clinic

Full name of responsible person

Dr. Zabihollah Shahmoradi

Street address

Khorram st.

City

Isfahan

Province

Isfahan

Postal code

8187698191

Phone

+98 31 3335 9933

Email

emrc@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Seyyed Hussein Bani Hashemi

Street address

Hezar jarib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

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Fax

+98 31 3668 0048

Email

researches@mui.ac.ir

Web page address

<https://mui.ac.ir/fa>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Fariba Iraj

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Latest degree
Subspecialist
Other areas of specialty/work

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iraji@med.mui.ac.ir

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

All data and variables are published except for patients' private information.

When the data will become available and for how long

Immediately after the article is published

To whom data/document is available

Professors and faculty members

Under which criteria data/document could be used

To better understand the article

From where data/document is obtainable

By emailing the corresponder author directly

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

After sending an email to the responsible writer and confirming the identity, it will be sent.

Comments