

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the effect of Triamcinolone 0.1% topical cream with sulfur 2% cream in the treatment of patients with hand eczema

Protocol summary

Study aim

Comparison of the average score of itching, burning, dryness and erythema of the hand before, 4 weeks after treatment and 4 weeks after follow-up in two groups

Design

Clinical trial with 2 comparative intervention groups without control group, with parallel groups, triple blind, randomized, phase 3 on 70 patients. For randomization, the patient chooses to use each cream for one hand.

Settings and conduct

The target population is all patients who refer to the skin clinic of Al-Zahra and Sedige Tahereh Hospital in Isfahan city with the complaint of hand eczema. In this study, there are ready-to-use creams in the market, which in order to create a three-way blinding of the study, under sterile conditions, the creams are poured into tubes without a printed brand, and the cream is named by the company as numbers 1 and 2, and until At the time of completion of the study, the patient and the project manager and the data analyst do not know the type of cream received, so that the study is triple-blinded.

Participants/Inclusion and exclusion criteria

Entry condition 1- All patients with hand eczema 2- Patients who have not been treated in the last month. Non-entry condition 1- There are patients who are taking another medicine 2- Patients who do not have the possibility to refer for the necessary follow-up 3- Patients who are accompanied by other skin diseases in the hand area other than eczema

Intervention groups

Each participant receives 2 creams. One of the creams contains Triamcinolone and the other cream contains sulfur, which the patient chooses to use one cream for the right hand and one cream for the left hand.

Main outcome variables

itching; burning; dryness; Erythema

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220306054206N2**

Registration date: **2022-12-26, 1401/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-26, 1401/10/05**

Update count: **0**

Registration date

2022-12-26, 1401/10/05

Registrant information

Name

Parisa Mohamadian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-03-20, 1401/12/29

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 sulfur 2% cream in the treatment of patients with hand eczema		Parallel
Public title	Comparison of the effect of Triamcinolone topical cream with sulfur cream in hand eczema	Other design features
Purpose	Treatment	Secondary Ids
Inclusion/Exclusion criteria		empty
Inclusion criteria:	All patients who have hand eczema and patients have not been treated in the last month.	Ethics committees
Exclusion criteria:	There are patients who are taking another medicine Patients who do not have the possibility to refer for the necessary follow-up Patients who have other accompanying skin disease in the hand area other than eczema	1
Age	No age limit	Ethics committee
Gender	Both	Name of ethics committee
Phase	3	Ethical Committee of Isfahan University of Medical Sciences
Groups that have been masked	- Participant - Care provider - Investigator - Outcome assessor - Data analyser - Data and Safety Monitoring Board	Street address
Sample size	Target sample size: 70 More than 1 sample in each individual Number of samples in each individual: 2 Each participant uses one cream for the right hand and another cream for the left hand	Hazar Jarib Street, Isfahan University of Medical Sciences and Health Services
Randomization (investigator's opinion)	Randomized	City
Randomization description	Since each patient uses two types of creams, and since the patient's right-handedness or left-handedness may affect the severity of each hand's eczema, it is up to the patient to choose the type of cream to use for each hand. so that randomization is done in this way and the intervention of the executive is removed from this process.	isfahan
Blinding (investigator's opinion)	Triple blinded	Province
Blinding description	To create triple blinding of the study, under sterile conditions, creams are poured into tubes without a printed brand, and the cream is named by the company as numbers 1 and 2, and until the completion of the study, the patient and the project manager and the data analyst are of the type The received cream is not aware so that the study is triple blinded	Isfahan
Placebo	Not used	Postal code
Assignment		81746-73461
		Approval date
		2022-11-14, 1401/08/23
		Ethics committee reference number
		IR.ARI.MUI.REC.1401.223
		Health conditions studied
		1
		Description of health condition studied
		eczema
		ICD-10 code
		L20.82
		ICD-10 code description
		Flexural eczema
		Primary outcomes
		1
		Description
		Itching score
		Timepoint
		4 weeks after treatment and 4 weeks after follow-up
		Method of measurement
		Itching is given a score from 1 to 10, and for each individual cream before treatment, after 4 weeks of treatment, and after 4 weeks of follow-up, patients' itching is scored in order to check the therapeutic effect of the drugs used.
		2
		Description
		Dryness score
		Timepoint
		4 weeks after treatment and 4 weeks after follow-up
		Method of measurement

Dryness is given a score from 1 to 10, and for each individual cream before treatment, after 4 weeks of treatment and after 4 weeks of follow-up, patients' dryness is scored in order to check the therapeutic effect of the drugs used.

3

Description

Burning score

Timepoint

4 weeks after treatment and 4 weeks after follow-up

Method of measurement

Burning is given a score from 1 to 10, and for each individual cream before treatment, after 4 weeks of treatment and after 4 weeks of follow-up, patients' burning is scored to check the therapeutic effect of the drugs used.

4

Description

Erythema score

Timepoint

4 weeks after treatment and 4 weeks after follow-up

Method of measurement

Erythema is given a score from 1 to 10, and for each individual cream before treatment, after 4 weeks of treatment and after 4 weeks of follow-up, patients' erythema is scored to check the therapeutic effect of the drugs used.

5

Description

Satisfaction with treatment

Timepoint

4 weeks after treatment and 4 weeks after follow-up

Method of measurement

To evaluate patients' satisfaction with treatment, Vas Score is recorded

6

Description

Eczema severity

Timepoint

Before the start of treatment, the end of 4 weeks of treatment and the end of 4 weeks of follow-up

Method of measurement

Hand eczema severity index (HECSI) score is used for patients.

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group uses triamcinolone cream

0.01% from Iran Daru factory twice a day for one month on the hands, and then the use is stopped and follow-up is carried out for the next month.

Category

Treatment - Drugs

2

Description

The second intervention group uses 2% sulfur cream made by A2Z company locally 2 times a day in the hands and then stops using the cream and is followed up for the next month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Al-Zahra and Sedige Tahereh Hospital, Isfahan

Full name of responsible person

Parisa Mohammadian

Street address

Hazar Jarib St., University of Medical Sciences and Health Care Services

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Asgari

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
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Full name of responsible person
Parisa Mohammadian
Position
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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

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the publication of the results

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

If they have documentation of conducting research in this field, the documentation will be provided

From where data/document is obtainable

To receive the data/document from the email address of the main author

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

Documents will be provided within a maximum of one month from the time of sending the requester's email

Comments