# 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**
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Iran (Islamic Republic of)
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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

**Public title**
Comparison of the effect of Triamcinolone topical cream with sulfur cream in hand eczema
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
All patients who have hand eczema and patients have not been treated in the last month.
**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
**Age**
No age limit
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**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
**Randomization (investigator's opinion)**
Randomized
**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.
**Blinding (investigator's opinion)**
Triple blinded
**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
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethical Committee of Isfahan University of Medical Sciences
**Street address**
Hazar Jarib Street, Isfahan University of Medical Sciences and Health Services
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isfahan
**Province**
Isfehan
**Postal code**
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
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## Sponsors / Funding sources

**1**

**Sponsor**
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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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resident
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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**
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**