

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of topical N-acetyl cysteine cream versus topical corticosteroid on treatment of chronic eczema of the hand: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of topical oatmeal cream versus topical placebo cream on the treatment of chronic eczema of the hand

Design

This is a double-blind randomized clinical trial, phase II, in which 70 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

Setting and conduct: The eligible patients with chronic eczema of the hand who will refer to Sina Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded so that the shape of the two types of cream will be similar and patients will not be aware of the type of cream they use. In addition, the assignment of the patients to the intervention and control groups will be done by a third person, therefore, the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 12 to 65 years; Chronic eczema of the hand Exclusion criteria: Pregnancy or breastfeeding; Other concurrent skin lesions such as psoriasis; Immunodeficiency

Intervention groups

Intervention group: Topical Fluocinolone cream 25% (Manufactured by Behvarzan Pharmaceutical Company) plus topical oatmeal cream 1% (Manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) for 2 weeks and then topical oatmeal cream 1% alone for 4 weeks Control group: Topical Fluocinolone cream 25% (Manufactured by Behvarzan Pharmaceutical Company) plus topical placebo cream (Manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) for 2 weeks

and then topical placebo cream alone for 4 weeks

Main outcome variables

Primary outcome: The severity of pruritus, The severity of skin lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N257**

Registration date: **2019-01-13, 1397/10/23**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-28, 1398/09/07**

Update count: **1**

Registration date

2019-01-13, 1397/10/23

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-31, 1397/10/10

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of topical N-acetyl cysteine cream versus topical corticosteroid on treatment of chronic eczema of the hand: a double-blind randomized clinical trial

Public title
Effect of topical N-acetyl cysteine cream versus topical corticosteroid on treatment of chronic eczema of the hand

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 12 to 65 years; Chronic eczema of the hand
Exclusion criteria:
Pregnancy or breastfeeding; Other concurrent skin lesions such as psoriasis; Immunodeficiency

Age
From **12 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The shape of the medications will be perfectly the same in the two groups. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double-blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-09-01, 1397/06/10

Ethics committee reference number

IR.UMSHA.REC.1397.398

Health conditions studied

1

Description of health condition studied

Eczema

ICD-10 code

L20.84

ICD-10 code description

Intrinsic (allergic) eczema

Primary outcomes

1

Description

The severity of pruritus

Timepoint

Before the intervention and 2 and 6 weeks after the intervention

Method of measurement

By taking history

2

Description

The severity of skin lesions

Timepoint

Before the intervention and 2 and 6 weeks after the intervention

Method of measurement

By clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Topical Flucinolone cream 25% (Manufactured by Behvarzan Pharmaceutical Company) plus topical oatmeal cream 1% (Manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) for 2 weeks and then topical oatmeal cream 1% alone for 4 weeks

Category

Treatment - Drugs

2

Description

Control group: Topical Flucinolone cream 25% (Manufactured by Behvarzan Pharmaceutical Company) plus topical placebo cream (Manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) for 2 weeks and then topical placebo cream alone for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Hamadan City

Full name of responsible person

Masa Hojati

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

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hojati90@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Masa Hojati

Position

Student of pharmacy

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Maryam Mehrpooya

Position

Pharmacologist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology