

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of educational program versus control group on the treatment of patients with chronic contact hand dermatitis: a single-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of educational program versus control group on the treatment of patients with chronic contact hand dermatitis

Design

This is a single-blind randomized clinical trial with control group, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct

This study will be performed in the Sina Hospital in Hamadan city on 90 eligible patients with chronic contact hand dermatitis. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be single-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 65 years Chronic contact dermatitis for at least 6 months Middle school and higher education Exclusion criteria: Pregnancy Other skin diseases such as psoriasis, lupus or dermatomiosis Use of topical or systemic corticosteroids in the past week Use of immunosuppressive drugs in the past three months

Intervention groups

Intervention group: Routine treatment of contact dermatitis plus care education program (including how to wash hands, dry hands, use moisturizing cream, wear gloves) for 45 minutes once every two weeks for 12 weeks Control group: Routine treatment of contact dermatitis

Main outcome variables

Primary outcome: Improvement of chronic hand contact dermatitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N439**

Registration date: **2022-08-29, 1401/06/07**

Registration timing: **prospective**

Last update: **2022-08-29, 1401/06/07**

Update count: **0**

Registration date

2022-08-29, 1401/06/07

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of educational program versus control group on the treatment of patients with chronic contact hand dermatitis: a single-blind randomized clinical trial

Public title

Effect of educational program versus control group on the treatment of patients with chronic contact hand dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 65 years Chronic contact dermatitis for at least 6 months Middle school and higher education

Exclusion criteria:

Pregnancy Other skin diseases such as psoriasis, lupus or dermatomiosis Use of topical or systemic corticosteroids in the past week Use of immunosuppressive drugs in the past three months

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Single blinded

Blinding description

The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as single-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

2022-08-20, 1401/05/29

Ethics committee reference number

IR.UMSHA.REC.1401.465

Health conditions studied

1

Description of health condition studied

Contact dermatitis

ICD-10 code

L23

ICD-10 code description

Allergic contact dermatitis

Primary outcomes

1

Description

Severity of chronic hand contact dermatitis

Timepoint

In the first, sixth and twelfth weeks after the intervention

Method of measurement

By taking history and clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment of contact dermatitis plus care education program (including how to wash hands, dry hands, use moisturizing cream, wear gloves) for 45 minutes once every two weeks for 12 weeks

Category

Treatment - Other

2

Description

Control group: Routine treatment of contact dermatitis

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Hamadan city

Full name of responsible person

Saba Beigiparast

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

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+98 81 3827 4184

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sababeigiparast@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Saba Beigiparast

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Dermatologist

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for updating data

poorolajal@umsha.ac.ir

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

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Email

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