

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparison of the effect of Vaseline, honey, and honey-Vaseline combination versus control group on the severity of hand eczema: a randomized clinical trial

#### Protocol summary

##### Study aim

To compare the effect of Vaseline, honey, and honey-Vaseline combination versus control group on the severity of hand eczema

##### Design

This is a randomized clinical trial, phase II, in which 128 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible patients with eczema referring to the Besat 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 block randomization.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Hand eczema, Exclusion criteria: Pregnancy or breastfeeding, Using corticosteroid or immunosuppressive drugs in the past month

##### Intervention groups

Intervention group 1: Topical ointment including Vaseline every 12 hours for 4 weeks Intervention group 2: Topical ointment including honey every 12 hours for 4 weeks Intervention group 3: Topical ointment including honey-Vaseline combination every 12 hours for 4 weeks Control: Receive no ointment.

##### Main outcome variables

Primary outcome: The severity of eczema

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N357**

Registration date: **2020-06-03, 1399/03/14**

Registration timing: **retrospective**

Last update: **2020-06-03, 1399/03/14**

Update count: **0**

##### Registration date

2020-06-03, 1399/03/14

##### 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

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-13, 1399/01/25

##### Expected recruitment end date

2020-05-14, 1399/02/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of Vaseline, honey, and honey-Vaseline combination versus control group on the severity of hand eczema: a randomized clinical trial

##### Public title

Comparison of the effect of Vaseline, honey, and honey-

Vaseline combination versus control group on the severity of hand eczema

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age of 18 to 65 years, Hand eczema,

**Exclusion criteria:**

Pregnancy or breastfeeding, Using corticosteroid or immunosuppressive drugs in the past month

**Age**

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

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **128**

**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 eight sheets of paper, writing on two sheets the name of the intervention 1 and on two sheets the name of the intervention 2 and on two sheets the name of intervention 3 and on two sheets the name of 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 eight sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****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**

2020-04-11, 1399/01/23

**Ethics committee reference number**

IR.UMSHA.REC.1399.053

**Health conditions studied****1****Description of health condition studied**

Eczema

**ICD-10 code**

B00.0

**ICD-10 code description**

Eczema herpeticum

**Primary outcomes****1****Description**

The severity of eczema

**Timepoint**

Before the intervention and 2 and 4 weeks after that

**Method of measurement**

Through the physical examination and using Hexy  
Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group 1: Topical ointment including Vaseline  
every 12 hours for 4 weeks

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2: Topical ointment including honey  
every 12 hours for 4 weeks

**Category**

Treatment - Drugs

**3****Description**

Intervention group 3: Topical ointment including honey-  
Vaseline combination every 12 hours for 4 weeks

**Category**

Treatment - Drugs

#### 4

**Description**

Control:Receive no ointment.

**Category**

N/A

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Besat Hospital in Hamadan city

**Full name of responsible person**

Mehran Mohammadi

**Street address**

Besat Hospital, Shahed Square

**City**

Hamadan

**Province**

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**Postal code**

6517838695

**Phone**

+98 81 3364 0030

**Email**

mehranmohammadi20@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 Fahmideh Ave

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info.research@umsha.ac.ir

**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**

Mehran Mohammadi

**Position**

Student of Nursery

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

School of Nursing and Midwifery, 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. Khodayar Oshvandi

**Position**

Nursing Education Specialist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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oshvandi2005@yahoo.com

## 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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**Phone**

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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