Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the effectiveness of a topical herbal product (Myrtus communis L., Lawsonia inermis L., Ziziphus spina-christi) compared to a topical betamethasone ointment on the severity of clinical symptoms in patients with hand eczema: A randomized controlled clinical trial

Protocol summary

Study aim
To determine the effectiveness of a topical herbal product compared to topical betamethasone ointment on the severity of clinical symptoms in patients with hand eczema.

Design
Randomized, controlled, parallel, double-blind ,phase 3 clinical trial on 88 patients . Randomized block assignment of four by R software.

Settings and conduct
Patients of educational and therapeutic centers in Gorgan who have hand eczema; Its severity is determined by dermatologist's clinical opinion and Hand Eczema Severity Index (HECSI) ; First, a checklist including demographic information and past disease history and medical history; Then matching the inclusion and exclusion criteria, and completing a written and informed consent; Then a description of the current disease and clinical symptoms, a quality of life questionnaire, a Mizaj questionnaire; Then random assignment to two groups؛ Then giving a pack of lifestyle recommendations, emollient cream, and glycerin soap to all participants; And ointment A or B Follow-up of the patient's condition and possible complications during the implementation of the project; Visits are one month and six weeks after the start

Participants/Inclusion and exclusion criteria
Inclusion: Patients aged 18-60 years, with moderate or mild hand eczema requiring treatment, who had not received any topical medication for 14 days prior to the study; Patients who consented to participate in the study. Exclusion: Other skin disease؛ Pregnant and lactating mothers؛ End-stage renal or hepatic disease؛ Use of systemic corticosteroids or immunosuppressants within the last 8 weeks؛ Local infection at the site of eczema

Intervention groups
Intervention: Receiving herbal ointment
Control:Receiving betamethasone ointment

Main outcome variables
Clinical improvement of hand eczema symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250428065504N1**
Registration date: **2025-07-11, 1404/04/20**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-11, 1404/04/20**
Update count: **0**

Registration date
2025-07-11, 1404/04/20

Registrant information

Name
Faegheh Hasanzadeh

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
2025-06-22, 1404/04/01

Expected recruitment end date
2026-02-20, 1404/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effectiveness of a topical herbal product (Myrtus communis L., Lawsonia inermis L., Ziziphus spina-christi) compared to a topical betamethasone ointment on the severity of clinical symptoms in patients with hand eczema: A randomized controlled clinical trial

Public title
Evaluating the effectiveness of a topical herbal product (Myrtus communis L., Lawsonia inermis L., Ziziphus spina-christi) compared to a topical betamethasone ointment on hand eczema
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18-60 years Patients with hand eczema with mild involvement need treatment or moderate Patients with hand eczema who have not received any topical medication for 14 days prior to the study Patients who consent to participate in the study.
Exclusion criteria:
Having another skin disease Presence of end-stage underlying liver or kidney disease Pregnant and lactating mothers Use of systemic corticosteroids or immunosuppressants within the last 8 weeks Local infection at the site of eczema
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
People who meet the entry criteria and do not meet the non-entry criteria and agree to participate in the study will be randomly assigned to one of two treatment groups based on block-of-four allocation. These blocks have 2 letters, A and B, and each letter has two repetitions. The number of blocks of 4 is equal to 22, whose sequence is produced by R software.
Blinding (investigator's opinion)
Double blinded
Blinding description
Study ointments are similar to the extent that is technically possible, and the tubes of herbal ointment and cortisone are identical and have A or B labels. The participants are randomly placed in one of the two groups receiving medicine A or B. The researcher, the participant and the medical personnel who provide the medicine to the patient do not know the content of ointment A or B. Also, the data in two groups A and B will be collected and provided to the statistician for analysis.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Golestan University of Medical Sciences
Street address
No. 4, Diamond 2 Building,103/2 Edalat Alley,Naharkhoran Blvd
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Gorgan
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Golestan
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Approval date
2025-03-09, 1403/12/19
Ethics committee reference number
IR.GOUMS.REC.1404.049

Health conditions studied

1

Description of health condition studied
Hand eczema
ICD-10 code
L23.9
ICD-10 code description
Allergic contact dermatitis, unspecified cause

Primary outcomes

1

Description
Itching severity
Timepoint
At the beginning of the study and one month after the

start of treatment

Method of measurement

Visual Analog Scale

2

Description

Erythema

Timepoint

At the beginning of the study and one month after the start of treatment

Method of measurement

Hand Eczema Severity Index(HECSI)

3

Description

Irritation

Timepoint

At the beginning of the study and one month after the start of treatment

Method of measurement

Visual Analog Scale(VAS)

4

Description

Dryness, cracking, and peeling skin

Timepoint

At the beginning of the study and one month after the start of treatment

Method of measurement

Hand Eczema Severity Index

5

Description

Papule

Timepoint

At the beginning of the study and one month after the start of treatment

Method of measurement

Hand Eczema Severity Index

Secondary outcomes

1

Description

Quality of life

Timepoint

At the beginning of the study and one month after the start of treatment

Method of measurement

Dermatology Life Quality Index

Intervention groups

1

Description

Intervention group: Herbal topical product (Myrtus communis L., Lawsonia inermis L., Ziziphus spina-christi) with a concentration of 1.5%, once a night at the site of eczema. Made by Niak Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Control group: Topical betamethasone ointment 0.1%, once a night in the eczema site. Manufactured by Niak Pharmaceutical Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Deziani Specialized and Subspecialty Clinic

Full name of responsible person

Ali Rezaee nejad

Street address

Deziani Specialized and Subspecialty Clinic, Opposite Behesht 17, Shahid Beheshti Street

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2

Recruitment center

Name of recruitment center

Sayad Shirazi hospital

Full name of responsible person

Moghadaseh Jahanshahi

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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Faegheh Hasanzadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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Person responsible for updating data

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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
Not applicable

Data Dictionary
Not applicable