Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of Mamogol cream in comparison with Hydrocortisone 1% on mild to moderate hand irritant contact dermatitis, clinical trial

Protocol summary

Study aim

Primary Objective: To determine the efficacy of Mamogel cream compared with 1% hydrocortisone ointment in reducing symptoms of mild to moderate irritant contact dermatitis of the hands.

Design

A phase III randomized, double-blind, parallel-group clinical trial will be conducted on 90 patients, including an intervention group and a control group. Randomization will be performed using the Random Allocation Software.

Settings and conduct

Patients with mild to moderate hand eczema at Hazrat Rasool Hospital and Behesht Health Center apply their medication for two weeks. The patients are blinded and receive the medication through sealed envelopes

Participants/Inclusion and exclusion criteria

Inclusion Criteria: - Individuals aged 12–65 years, diagnosed with mild to moderate irritant contact dermatitis of the hands by a dermatologist, based on the Hand Eczema Severity Index (HECSI) classification system. - Patients who have not received medical treatment for hand dermatitis for at least one week prior to enrollment, and have not used topical corticosteroids during the past week. Exclusion Criteria: - Patients reporting a history of allergy to Althaea officinalis (marshmallow plant). - Patients currently receiving other corticosteroid medications, antibiotics, or skin-drying agents such as isotretinoin (Roaccutane).

Intervention groups

The intervention group consists of patients with mild to moderate hand eczema who receive Mamogel cream. The comparison group includes patients with mild to moderate hand eczema who receive 1% hydrocortisone ointment.

Main outcome variables

HECSI Score, Quality of life, Recurrence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250923067342N1**
Registration date: **2025-11-18, 1404/08/27**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-18, 1404/08/27**
Update count: **0**

Registration date

2025-11-18, 1404/08/27

Registrant information

Name

Zahra sadat Akhlaghi Kalahrodi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-17, 1404/07/25

Expected recruitment end date

2026-10-17, 1405/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of Mamogol cream in comparison with Hydrocortisone 1% on mild to moderate hand irritant contact dermatitis, clinical trial

Public title
Evaluation of the effect of Mamogol cream on mild to moderate hand irritant contact dermatitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Individuals aged 12–65 years of both sexes, diagnosed with mild to moderate irritant contact dermatitis of the hands by a dermatologist, based on the Hand Eczema Severity Index (HECSI) classification system Patients who have not received any medical treatment for hand dermatitis for at least one week prior to enrollment, and who have not used topical corticosteroids during the past week. Patients evaluated according to Traditional Persian Medicine principles, with a comprehensive TPM history obtained at the outset of the study. Provision of written informed consent.

Exclusion criteria:
Patients reporting a history of allergy to Althaea officinalis Patients currently receiving other corticosteroid medications, antibiotics, or skin-drying agents such as isotretinoin (Roaccutane). Patients unwilling to discontinue use of these medications. Patients with very severe hand dermatitis, with a HECSI (Hand Eczema Severity Index) score above 117, according to the classification system Patients with uncontrolled systemic cardiovascular, respiratory, hematologic, urinary, autoimmune, infectious diseases, or diabetes mellitus. Pregnant or breastfeeding women.

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
After obtaining informed consent, patients are randomly assigned to two groups. Randomization is performed using the Random Allocation Software through a block randomization method with randomly generated blocks. To ensure allocation concealment, sealed envelopes are employed: the patient’s identification number is written on the outside of each envelope, while the assigned study group is indicated inside. Each patient opens his or her respective envelope to determine group allocation

Blinding (investigator's opinion)
Double blinded

Blinding description
The creams will be dispensed in identical, unlabeled containers.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

Street address
Hemmat

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2025-09-17, 1404/06/26

Ethics committee reference number
IR.iums.rec.1404.636

Health conditions studied

1

Description of health condition studied
mild to moderate Irritant contact dermatitis of hand

ICD-10 code
L24

ICD-10 code description
Irritant contact dermatitis

Primary outcomes

1

Description
Severity of dermatitis symptoms

Timepoint
Effect of Mamogel cream after two weeks of use, and assessment of disease recurrence two weeks after discontinuation of the medication

Method of measurement
Severity of dermatitis symptoms is assessed based on patient self-report using the standard Hand Eczema Severity Index (HECSI) questionnaire.

Secondary outcomes

1

Description
Incidence and type of adverse effects observed during treatment.
Timepoint
Assessments will be performed at baseline, after completion of treatment, and two weeks after treatment discontinuation.
Method of measurement
Based on patient self-report and according to the CTCAE questionnaire

2

Description
Quality of life
Timepoint
Assessments will be performed at baseline, after completion of treatment, and two weeks after treatment discontinuation.
Method of measurement
Based on patient self-report by completing the standard DLQI questionnaire

3

Description
Recurrence of symptoms two weeks after completion of treatment
Timepoint
two weeks after completion of treatment
Method of measurement
Based on patient self-report by completing the standard HECSI questionnaire

Intervention groups

1

Description
Intervention group: Patients apply Mamogel cream (produced by Goldaroo Pharmaceutical Company) topically to the affected area twice daily for two consecutive weeks
Category
Treatment - Drugs

2

Description
Control group: Patients apply 1% hydrocortisone ointment to the affected area twice daily for two weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasool Hospital
Full name of responsible person
Zahra sadat Akhlaghi
Street address
Sattarkhan
City
Tehran
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1445613131
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr jamshidi
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1114733311
Phone
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Email
info.irantms@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Iran 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
Iran University of Medical Sciences

Full name of responsible person
zahra sadat akhlaghi

Position
PHD Candidate

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available