

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Efficacy of topical herbal cream formulation consisting of borage, evening primrose, calendula and, leeks versus topical mometasone 0.01% in the treatment of atopic dermatitis

Protocol summary

Study aim

Comparison of the effect of herbal cream formulation consisting of borage, evening primrose, calendula, and leeks with topical mometasone 0.01% t in the treatment of atopic dermatitis

Design

Phase-3 double-blind randomized controlled trial, with parallel groups on 62 patients. Simple randomization will be performed using a table of random numbers

Settings and conduct

Patients with atopic dermatitis will be selected based on the inclusion and exclusion criteria from those attending the Dermatology Clinics of Al-Zahra and Sedighe Tahereh Hospitals affiliated with Isfahan University of Medical Sciences. Patients will be randomized into two groups using simple randomization. The two drugs will be prepared in similar shape and form by a colleague (blinding of the patients) and delivered to the visiting physician so that the physician will also be blinded to the groupings. Patients will receive treatment daily for a month and the drug will be tapered within the next month. All patients will be visited 4 times (weeks 0, 4, 8, and 16) by the physician and will be evaluated regarding SCORAD score. Also, patients will be asked to rate their satisfaction with treatment from 0 to 10 at 4, 8, and 16 weeks using visual analogue scale (VAS).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age >7 years SCORing Atopic Dermatitis (SCORAD) score <50 Exclusion criteria: Accompanying physical illness Any physical illness preventing drug administration Treatment in the past 6 months Drug use or alcohol consumption in the past 6 months Pregnancy or lactation Lack of following up by the patient Severe drug hypersensitivity

Intervention groups

One group a herbal combination cream and the other group topical mometasone

Main outcome variables

Improvement in SCORing Atopic Dermatitis (SCORAD) score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211216053428N1**

Registration date: **2022-02-22, 1400/12/03**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-22, 1400/12/03**

Update count: **0**

Registration date

2022-02-22, 1400/12/03

Registrant information

Name

Faeze Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3131

Email address

mousavi_faeze97@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-20, 1400/10/30

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of topical herbal cream formulation consisting of borage, evening primrose, calendula and, leeks versus topical mometasone 0.01% in the treatment of atopic dermatitis

Public title

Herbal cream of borage, evening primrose, calendula, and leek versus topical mometasone 0.01% for atopic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age >7 years SCORAD score <50

Exclusion criteria:

Accompanying physical illness Any physical illness preventing drug administration Treatment in the past 6 months Drug use or alcohol consumption in the past 6 months Pregnancy or lactation Lack of following up by the patient Severe drug hypersensitivity

Age

From **7 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual simple randomization using a table of random numbers generated by the Random Allocation software by a statistician unaware of the study. To perform allocation concealment, the same statistician will write the name of the groups on a piece of paper and put them in numbered envelopes based on the randomization table. The envelopes will then be sealed. Patient recruitment will be done by the investigator blinded to the content of the envelopes. An envelope will be allocated to each patient upon entering the study and the investigator will be unaware of which group the next patient will be allocated to.

Blinding (investigator's opinion)

Double blinded

Blinding description

The physician responsible for lesion assessment will be blinded to the grouping of patients. Both drugs will be available in unidentifiable forms to the patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

School of Medicine - Isfahan University of Medical Sciences (Research Ethics Committee)

Street address

Isfahan University of Medical Sciences, Hazar Jerib, Isfahan

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2021-08-15, 1400/05/24

Ethics committee reference number

IR.MUI.MED.REC.1400.379

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

Atopic dermatitis

ICD-10 code

L20

ICD-10 code description

Atopic dermatitis

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

Improvement in SCORing Atopic Dermatitis (SCORAD)

Timepoint

Weeks 0, 4, 8, and 12

Method of measurement

SCORing Atopic Dermatitis (SCORAD)

Secondary outcomes**1****Description**

Patient satisfaction with treatment

Timepoint

Weeks 4, 8, and 16

Method of measurement

10-item visual analogue scale (VAS)

Intervention groups

1

Description

Intervention group: topical herbal cream consisting of borage, evening primrose, calendula, and leeks daily for a month and tapered during the next month

Category

Treatment - Drugs

2

Description

Control group: topical mometasone 0.01% daily for a month and tapered during the next month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sedigheh tahere clinic

Full name of responsible person

Faeze Mousavi

Street address

Khorram street

City

Isfahan

Province

Isfahan

Postal code

8484144374

Phone

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Email

mousavi_faeze97@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellery of Research and Technology, Isfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

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Hazar Jerib St.

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research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellery of Research and Technology, Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Faeze Mousavi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Others

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No 114, Emam Blvd., Sharifabad St., Mobarakeh, Zibashahr

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Azam Mousavi

Position

Resident of Dermatology

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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

Esfahan University of Medical Sciences

Full name of responsible person

Faeze Mousavi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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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