

# 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 Atomic 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

+98 31 3339 0101

##### 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

##### Street address

Hazar Jerib St.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

##### Phone

+98 31 3668 8138

##### Email

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

##### Street address

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

##### City

Mobarakeh

##### Province

Isfahan

##### Postal code

8484144374

##### Phone

+98 31 5254 3385

##### Email

mousavi\_faeze97@yahoo.com

## 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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**Email**

mousavi\_faeze97@yahoo.com

**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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**Phone**

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**Email**

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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