

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trial of efficacy of a herbal cream containing *Fumaria officinalis* and *Silybum marianum* in the treatment of eczema; Double-blind controlled Trial.

Protocol summary

Study aim

Evaluating the efficacy of topical herbal cream on the symptoms management of Eczema (clinical study) and it's comparison with Mometasone 0.1%

Design

A randomized, double-blinded, sham controlled phase2 clinical trial with a parallel group design of 66 patients

Settings and conduct

The clinical part of this study is performed in the dermatology clinic of Al-Zahra hospital in Esfahan. The blinding of the study is done in a way that the containers are labeled by the researcher, and patients are initially told that when you participate in the project, you are randomly given a herbal or chemical cream, so the patient is And the doctor is not aware of the consumed content. The data is also shown to Code Specialist A through Code B to blind him to the research. This clinical trial is randomized, double-blinded, controlled trial with a parallel group design of 66 patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Men and women 18 years or older - One or more eczema lesions - Patients who have not received topical, oral, or injectable medications for the treatment of eczema in the past week -Lack of infection or malignancy at the site of treatment (no problem with closed wounds). Exclusion criteria include: Under 18 years- Pregnancy and lactation- Patients with other skin lesions - Patients taking systemic immunosuppressive drugs or biological drugs.

Intervention groups

Herbal cream (intervention group) or mometasone cream (control group)

Main outcome variables

There will be no consequences for the participants.

General information

Reason for update

Added total of final patients number

Acronym

IRCT registration information

IRCT registration number: **IRCT20181026041466N5**

Registration date: **2020-09-27, 1399/07/06**

Registration timing: **prospective**

Last update: **2021-12-23, 1400/10/02**

Update count: **1**

Registration date

2020-09-27, 1399/07/06

Registrant information

Name

Ali Aghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 8149

Email address

ali.aghaei110@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-06, 1399/07/15

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

2020-10-06, 1399/07/15

Actual recruitment end date

2021-01-19, 1399/10/30

Trial completion date

2021-01-29, 1399/11/10

Scientific title

Clinical trial of efficacy of a herbal cream containing Fumaria officinalis and Silybum marianum in the treatment of eczema; Double-blind controlled Trial.

Public title

Effect of topical herbal cream on Eczema and it's comparison with Mometasone 0.1%

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 years old Men and women or older One or more eczema lesions Patients who have not received topical, oral, or injectable medication for the treatment of eczema in the last week Lack of infection or malignancy at the treatment site (no problem with closed wounds) Patient's consent to participate in the study

Exclusion criteria:

Under 12 years old Pregnancy and lactation Patients with other skin lesions Patients taking immunosuppressive systemic drugs or biological drugs

Age

From **12 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **66**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed in a randomized, individualized, block with statistical software. The randomization list is available to the researcher. and given to the participants, according to the order of the herbal cream (intervention group) or the mometasone cream (control group). The herbal cream containers are labeled blue and the mometasone cream containers are labeled red; shown in the randomization list in letters A and B, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

The blinding of the study is done in a way that the labels of the medicine containers are labeled by the researcher, and patients are initially told that when you participate in the project, you are randomly given a herbal or chemical cream, so Patient and physician are not aware of consumed content. The data is also shown to the data analyzer by code A and B.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Road

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2020-09-26, 1399/07/05

Ethics committee reference number

IR.AJUMS.REC.1399.487

Health conditions studied

1

Description of health condition studied

Eczema

ICD-10 code

L20

ICD-10 code description

Atopic dermatitis

Primary outcomes

1

Description

Atopic dermatitis disease intensity

Timepoint

At the beginning of the study and about 30 days after starting the topical cream (after treatment)

Method of measurement

SCORAD Index form

2

Description

Duration of recovery

Timepoint

About 30 days after starting the topical cream (after treatment)

Method of measurement

Patient Tracking and Evaluation with SCORAD and DLQI

Secondary outcomes

1

Description

Quality of dermatology patient's life

Timepoint

At the beginning of the study and about 30 days after starting the topical cream (after treatment)

Method of measurement

DLQI questionnaire

Intervention groups

1

Description

Intervention group: The group receiving the herbal cream made by a researcher at the Ahvaz pharmacy School in Iran, every night until healing.

Category

Treatment - Drugs

2

Description

Control group: The group receiving the Momtazone 0.1% cream manufactured by Kish Medifarm Company in Iran, applied for 3 weeks every night until they heal.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Fariba Iraj

Street address

Alzahra Hospital, Soffeh Blvd

City

Isfahan

Province

Isfahan

Postal code

8179604891

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Alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rayka raya teb co

Full name of responsible person

Ali aghaei

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Ansar, Koote abdollah.

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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

Rayka raya teb co

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Ali Aghaei

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Position

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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