Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Clinical trial of efficacy of a herbal cream containing Fumaria officinalis and Silybum marianum in the treatment of eczema; Double-blind controled 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 controled 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 Iraji
Street address
Alzahra Hospital, Soffeh Blvd
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8179604891
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rayka raya teb co
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Ali aghaei
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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
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Medical Pharmacy
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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
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