

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Double-blind placebo-controlled clinical trial of Boswellia serrata extract in the treatment of atopic eczema

Protocol summary

Study aim

The aim of this study is the evaluation of Boswellia serrata extract cream on patients with atopic Eczema

Design

This study was a double-blind, controlled trial, 33 patients with atopic eczema were assigned in each group. For randomization, the permuted block randomization will be used with quadruple blocks, In order to apply the concealment in the randomization process, unique codes, which is generated by the software, will be used on the drug boxes.

Settings and conduct

All patients referred to Imam Khomeini Hospital of Ahvaz, Iran, were assigned randomly in one of the placebo and treatment groups for 2 weeks

Participants/Inclusion and exclusion criteria

Inclusion criteria: Atopic ezema, not pregnancy, non lactation, not using oral and topical medication for treatment Exclusion criteria: Occurrence of local infection, occurrence to other skin diseases, drug sensitivity

Intervention groups

Intervention group: 33 patients with atopic Eczema, each receive herbal cream 3 times a day for 2 weeks Control group:33 patients with atopic Eczema, each receive placebo cream 3 times a day for 2 weeks

Main outcome variables

Edema Dryness Erythema Pruritus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111105008013N5**

Registration date: **2018-10-20, 1397/07/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-20, 1397/07/28**

Update count: **0**

Registration date

2018-10-20, 1397/07/28

Registrant information

Name

Amir Siahpoosh

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3334 2197

Email address

siahpoosh-a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double-blind placebo-controlled clinical trial of Boswellia serrata extract in the treatment of atopic eczema

Public title

Effect of frankincense in treatment of eczema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Atopic ezema Not pregnancy Non lactation Not using oral and topical medication for treatment

Exclusion criteria:
Occurrence of local infection Occurrence to other skin diseases Drug sensitivity

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, the permuted block randomization will be used with quadruple blocks. blocks will be produced by using the online site (www.sealedenvelope.com).

Blinding (investigator's opinion)
Double blinded

Blinding description
Unique codes, which is generated by the software, will be used on the drug boxes. By entering each individual into the study based on the produced sequence, the drug box in which the code is registered, will be assigned to the individual. During the research, the randomization list is held by the statistic consultant, and the participants, the project implementer and all those who participate in the measurement of the indicators will not be aware of the assigned groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Road

City

Ahvaz

Province

Khouzestan

Postal code

6135733184

Approval date

2018-03-06, 1396/12/15

Ethics committee reference number

IR.AJUMS.REC.1396.1076

Health conditions studied

1

Description of health condition studied

Atopic eczema

ICD-10 code

L20

ICD-10 code description

Atopic dermatitis

Primary outcomes

1

Description

Edema

Timepoint

Start intervention and two week later

Method of measurement

According to severity was scored 0 to 3

2

Description

Dryness

Timepoint

Start intervention and two week later

Method of measurement

According to severity was scored 0 to 3

3

Description

Erythema

Timepoint

Start intervention and two week later

Method of measurement

According to severity was scored 0 to 3

4

Description

Pruritus

Timepoint

Start intervention and two week later

Method of measurement

According to severity was scored 0 to 3

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Herbal cream 3 times a day for 2 weeks

Category

Treatment - Drugs

2

Description

Control group: placebo cream 3 times a day for 2 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital

Full name of responsible person

Amir Siahpoosh

Street address

Bist-o Chahr Metri St

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Amirsiahpoosh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences,
medicinal plants research center

Full name of responsible person

Dr Mohamad badavi

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amirsiahpoosh@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jundishapur University of Medical Sciences,
medicinal plants research center

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

Ahvaz University of Medical Sciences

Full name of responsible person

Amir Siahpoosh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only a part of the data will be shared

When the data will become available and for how long

The access period will be 6 months after the publication of the results

To whom data/document is available

The obtained data from current study will be available only for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Six months after the publication of this study papers, the obtained data will be available to the applicant researchers for further analysis

From where data/document is obtainable

Applicants can be contacted with corresponding author by e-mail

What processes are involved for a request to access data/document

Applicants will be able to access the obtained data from current study by sending an email to the corresponding author up to one month

Comments