Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Double-blind placebo-controled 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

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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-controled 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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6193673111
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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
Street address
Ahvaz golestan road
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ahvaz
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Khouzestan
Postal code
6135733184
Phone
+98 61 3336 2414
Email
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
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Other areas of specialty/work
Medical Pharmacy
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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