Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of oral phytosome prepared from wild Pistacia atlantica oleoresin on symptomatic and spirometric improvement of patients with moderate to severe asthma compared with standard treatment: a randomized clinical trial

Protocol summary

Study aim
Evaluation of the effect of oral phytosome prepared from wild Pistacia atlantica oleoresin on symptomatic and spirometric improvement of patients with moderate to severe asthma compared with standard treatment

Design
A randomized clinical trial, triple blind, 104 patients enrolled and followed for four weeks

Settings and conduct
Patients diagnosed with moderate or severe asthm are randomly divided into groups receiving three doses of tablets (or oral capsules) and a placebo group.The patients are evaluated for 4 weeks and spirometry is recorded at the end of 4 weeks. The patients will be evaluated at asthma and allergy specialist office.

Participants/Inclusion and exclusion criteria
Inclusion: Patients aged 15 years and older who referred to the asthma and allergy specialist's office with a diagnosis of moderate or severe allergic asthma.
Exclusion: Having other respiratory diseases except asthma; Pregnant and lactating women; People with a history of drug allergy;Taking anti-leukotriene drugs; People who use supplements or other inhalation and non-inhalation drugs; Having special diseases

Intervention groups
1: Receiving placebo in addition to common treatment; 2: receiving the first dose of phytosome formulation containing wild pistachio oleoresin in addition to common treatment; 3: receiving the second dose of phytosome formulation containing wild pistachio oleoresin in addition to the common treatment; 4: receiving the third dose of phytosome formulation containing wild pistachio oleoresin in addition to common treatment

Main outcome variables
Times of waking up with an asthma attack during the past week; Severity of symptoms during the past week;The amount of restrictions in daily activities during the past week;The severity of breath during the past week; wheezing during the past week;The average number of daily puffs of short-acting inhaled bronchodilators used during the past week

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100420003760N5**
Registration date: **2022-11-08, 1401/08/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-08, 1401/08/17**
Update count: **0**

Registration date
2022-11-08, 1401/08/17

Registrant information

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Marzieh Rashidipour

Name of organization / entity
Lorestan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2022-10-30, 1401/08/08

Expected recruitment end date

2023-10-30, 1402/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral phytosome prepared from wild Pistacia atlantica oleoresin on symptomatic and spirometric improvement of patients with moderate to severe asthma compared with standard treatment: a randomized clinical trial

Public title

Phytosome prepared from wild Pistacia Atlantica oleoresin on symptomatic and spirometric improvement of patients with asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 15 years and older referring to the asthma and allergy specialist's office with a diagnosis of moderate or severe allergic asthma

Exclusion criteria:

Having other respiratory diseases except asthma Pregnant and lactating women or with a desire to become pregnant People with a history of drug allergy Taking anti-leukotriene drugs People who use supplements or other inhalation and non-inhalation drugs beyond what is allowed in this study. Having other special diseases such as kidney disease, tumor, etc.

Age

From **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of patients into four groups and also using stratified random allocation. In this way, classes are made based on age group (below 40 years and older or equal to 40 years), gender (male and female) and severity (moderate or severe). Within each class, random permutation blocks (8 blocks) are used to assign samples to the required groups. To create random sequences, letters A, B or C (corresponding to the experimental group) will be used as follows. A B C: 0-16 ACB : 17-32 B A C: 33-48 B C A: 49-64 C A B: 65-80 C B A: 81-96

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study is triple-blinded, the therapist (recorder of spirometry parameters and questioner of the clinical evaluation form), the patient and the data analyst are uninformed and the decoder is not a member of the research team.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Lorestan University of Medical Sciences

Street address

No 20, Anooshirvan Rezaei Square, Lorestan University of Medical Sciences

City

Khorramabad

Province

Lorestan

Postal code

6816889468

Approval date

2021-05-18, 1400/02/28

Ethics committee reference number

IR.LUMS.REC.1400.050

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

The times of waking up with an asthma attack during the past week (zero to six according to the questionnaire); The severity of symptoms during the past week (zero to six according to the questionnaire); The amount of restriction in daily activities during the past week (zero to six according to the questionnaire); the severity of

breath during the past week (zero to six according to the questionnaire); wheezing during the past week (zero to six according to the questionnaire).The daily puffs of short-acting inhaled bronchodilators used during the past week (zero to six according to the questionnaire)

Timepoint

Before, and after intervention. Spirometry time 0 and 30

Method of measurement

Through Asthma Control Questionnaire and spirometry.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receive the first dose(50) of phytosome formulation containing wild pistachio oleoresin in addition to conventional treatment

Category

Treatment - Drugs

2

Description

Intervention group: receive the second dose(100) of phytosome formulation containing wild pistachio oleoresin in addition to conventional treatment

Category

Treatment - Drugs

3

Description

Intervention group: receive the third dose(200) of phytosome formulation containing wild pistachio oleoresin in addition to conventional treatment

Category

Treatment - Drugs

4

Description

Control group: receive placebo in addition to conventional treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Asthma and allergy specialist office

Full name of responsible person

Marzieh Rashidipour

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No. 140, Razi Ave. Pajohandeh Blvd, Herbal Research Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

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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

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Marzieh Rashidipour
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
Environmental toxicology; Herbal medicine
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Only part of the data, such as information about the main consequence or similar, can be shared
When the data will become available and for how long
Start the access period 18 months after printing the results.
To whom data/document is available
Data will only be available to researchers working at academic and scientific institutions
Under which criteria data/document could be used
The data will only be used to inform the results of the study
From where data/document is obtainable
Lorestan University of Medical Sciences
What processes are involved for a request to access data/document
Refer to Lorestan University of Medical Sciences, Vice Chancellor of Research and Technology, Research Projects Department, Management of Research Projects Department, 066333120175, Mrs. Sajedi , fax:066333120173 call mrs. zarei 0989167083314
Comments