

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 asthma 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

Name

Marzieh Rashidipour

Name of organization / entity

Lorestan University of Medical Sciences

Country

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

Dr. Bahram Rasoulia

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

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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

Ph.D.

Other areas of specialty/work

Environmental toxicology; Herbal medicine

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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. zareei 0989167083314

Comments