

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation of the effect of sublingual soft gel containing *Pistacia atlantica* oleoresin essential oil on symptomatic and spirometric improvement of patients with moderate to severe asthma compared with standard treatment: A triple-blinded, randomized, placebo-controlled trial

Protocol summary

Study aim

Determining the effect of sublingual soft gel containing *Pistacia atlantica* oleoresin essential oil on symptomatic and spirometric improvement in patients with moderate to severe asthma compared to standard treatment: a randomized controlled clinical trial

Design

A controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 140 patients. The method of random allocation of eligible patients to the study groups is also using stratified random allocation

Settings and conduct

Patients diagnosed with moderate or severe asthma are randomly divided into groups receiving three doses of soft gel 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 in the office of a lung specialist in Shahid Rahimi Hospital in Khorramabad.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 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 criteria: 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 such as dialysis patients (hemophilia, thalassemia, and MS) and incurable (cystic fibrosis (CF), mucopolysaccharidosis (MPS), spinal muscular atrophy (SMA), metabolic diseases, and autism) lung cancer

Intervention groups

1- The group receiving common treatment and 200 mg sublingual soft gel containing 0 mg of *Pistacia atlantica* oleoresin essential oil. 2- The group receiving common

treatment and 200 mg sublingual soft gel containing 40 mg of *Pistacia atlantica* oleoresin essential oil. 3- The group receiving common treatment and 200 mg sublingual soft gel containing 75 mg of *Pistacia atlantica* oleoresin essential oil. 4- The group receiving common treatment and 200 mg sublingual soft gel containing 150 mg of *Pistacia atlantica* oleoresin essential oil.

Main outcome variables

Times of waking up with an asthma attack ; Severity of symptoms ; The amount of restrictions in daily activities; The severity of breath ; wheezing; 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: **IRCT20100420003760N7**

Registration date: **2023-04-17, 1402/01/28**

Registration timing: **prospective**

Last update: **2023-04-17, 1402/01/28**

Update count: **0**

Registration date

2023-04-17, 1402/01/28

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
2023-05-24, 1402/03/03

Expected recruitment end date
2024-06-23, 1403/04/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of sublingual soft gel containing Pistacia atlantica oleoresin essential oil on symptomatic and spirometric improvement of patients with moderate to severe asthma compared with standard treatment: A triple-blinded, randomized, placebo-controlled trial

Public title
Effect of sublingual soft gel of essential oil of Pistacia atlantica in asthma

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
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 criteria:
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 such as dialysis patients (hemophilia, thalassemia, and MS) and incurable (cystic fibrosis (CF), mucopolysaccharidosis (MPS), spinal muscular atrophy (SMA), metabolic diseases, and autism)
lung cancer

Age
From **15 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **35**

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 are used to assign samples to the required groups. To create random sequences, letters A, B, C or D (corresponding to the experimental group) will be used as follows. ABCD: 0-3 ABDC: 4-7 ACBD: 8-11 ACDB:12-15 . . DABC DBAC DCAB DCBA: 92-95 Then a corner of the table of random numbers is selected and two-digit numbers are read from top to bottom, and finally, according to the read number, a random sequence of letters A to D is registered in the desired floor. Finally, a random sequence of letters A to D (corresponding to the 4 experimental groups) will be created in each class of all existing classes, and the samples will be assigned to 4 groups based on this random sequence.

Blinding (investigator's opinion)

Triple blinded

Blinding description

A random sequence of letters A to D (corresponding to 4 experimental groups) will be created in each class from all the existing classes, and the samples will be assigned to 4 groups based on this random sequence. This study will be triple blind, which means that the pain intensity assessor, the patient and the data analyst are not aware of the type of treatment assigned to the patient. In addition, the decipherer is not a member of the research team, and the sublingual tablets in all groups are completely identical in appearance. Data registration in the statistical software and data analysis is done by the statistical consultant without mentioning the names of the groups.

Placebo

Used

Assignment

Parallel

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

2023-03-15, 1401/12/24

Ethics committee reference number

IR.LUMS.REC.1401.312

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)

Timepoint

Before, and after intervention. Spirometry time 0 and 30

Method of measurement

Through Asthma Control Questionnaire and spirometry.

2

Description

The severity of symptoms 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.

3

Description

The amount of restriction in daily activities 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.

4

Description

The severity of breath 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.

5

Description

Wheezing 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.

6

Description

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 group1: The group receiving common treatment and 200 mg sublingual soft gel containing 40 mg of Pistacia atlantica oleoresin essential oil (Soft gel is made according to the order of the project manager in Kashan Barij Essence Company)

Category

Treatment - Drugs

2

Description

Intervention group2: The group receiving common treatment and 200 mg sublingual soft gel containing 75 mg of Pistacia atlantica oleoresin essential (Soft gel is made according to the order of the project manager in Kashan Barij Essence Company).

Category

Treatment - Drugs

3

Description

Intervention group3: The group receiving common treatment and 200 mg sublingual soft gel containing 150 mg of Pistacia atlantica oleoresin essential oil (Soft gel is made according to the order of the project manager in Kashan Barij Essence Company)

Category

Treatment - Drugs

4

Description

Control group 1: The group receiving common treatment and 200 mg sublingual soft gel containing 0 mg of Pistacia atlantica oleoresin essential oil (Soft gel is made according to the order of the project manager in Kashan Barij Essence Company).

Category
Placebo

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 Rasoulilan

Street address

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

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Web page address

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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

Medical Nanotechnology

Street address

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

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Email

m_rashidi80@yahoo.com

Web page address

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Person responsible for scientific 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

Medical Nanotechnology

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Person responsible for updating data

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Marzieh Rashidipour
Position
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Latest degree
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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