Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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)

Phone

+98 916 667 4776

Email address
m.rashidipour@lums.ac.ir

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
Street address
No. 140, Razi Ave. Pajohandeh Blvd, Herbal Research Center
City
Khorramabad
Province
Lorestan
Postal code
6814989468
Phone
+98 66 3312 0172
Fax
+98 66 3312 0172
Email
m_rashidi80@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Dr.Bahram Rasoulian
Street address
No. 20, Anooshirvan Rezaei Square, Lorestan University of Medical Sciences
City
Khorramabad
Province
Lorestan
Postal code
6813833946
Phone
+98 66 3312 0172
Fax
+98 66 3312 0172
Email
m_rashidi80@yahoo.com
Web page address
http://research.lums.ac.ir/
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
City
Khorramabad
Province
Lorestan
Postal code
6814989468
Phone
+98 66 3312 0172
Fax
+98 66 3312 0172
Email
m_rashidi80@yahoo.com
Web page address
http://lums.ac.ir/

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
Street address
No. 140, Razi Ave. Pajohandeh Blvd, Herbal Research Center
City
Khorramabad
Province

Lorestan

Postal code
6814989468

Phone
+98 66 3312 0172

Fax
+98 66 3312 0172

Email
m_rashidi80@yahoo.com

Person responsible for updating data

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
Golshan 2 Ave. Enghelab Blvd.

City
Khorramabad

Province
Lorestan

Postal code
6816889468

Phone
+98 66 3312 0172

Fax
+98 66 3312 0172

Email
m_rashidi80@yahoo.com

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