

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Study the effect of Plantago major and Almond gum on clinical symptoms and Pulmonary function tests in patients with resistant to treat Asthma

Protocol summary

Study aim

Determine the effect of adding herbal compound based on Plantago major and almond gum on clinical symptoms and Pulmonary function tests in patients with resistant to treat Asthma

Design

In this study, 25 patients with resistant asthma who have inclusion criteria will be admitted to the Ghaem hospital and private clinics will be selected. It is a non-randomized, not-blind, nonplacebo-controlled, multicenter, Phase 2 clinical trial

Settings and conduct

The study is conducted in Ghaem hospital in Mashhad and private clinics and will not have blinding

Participants/Inclusion and exclusion criteria

Inclusion criteria is Resistant to treat Asthma in step 4 with A dry cough; Exclusion criteria are patients with Unstable asthma, Upper respiratory tract infection, Gut Obstruction, Pregnancy and lactation and Concurrent use of other immunosuppressive drugs

Intervention groups

Intervention is treatment with a therapeutic package containing plantain seed and Almond gum. Time of intervention is 4 weeks.

Main outcome variables

The study outcomes are reduction or improvement in Asthma symptoms regarding spirometry parameters, Asthma control test, and Asthma quality of life questionnaires.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012026117N1**

Registration date: **2017-01-31, 1395/11/12**

Registration timing: **prospective**

Last update: **2017-12-10, 1396/09/19**

Update count: **1**

Registration date

2017-01-31, 1395/11/12

Registrant information

Name

Masoumeh Kaboli Farshchi

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 2081

Email address

kabolifm911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of Plantago major and Almond gum on clinical symptoms and Pulmonary function tests in patients with resistant to treat Asthma

Public title

Effect of a herbal medicine combination in resistant to treat Asthma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with resistant to treat asthma who had often dry cough in their history

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 25

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Daneshgah Avenue, Central Building, Mashhad University of Medical Sciences, University Ethics Committee

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2016-06-11, 1395/03/22

Ethics committee reference number

IR.MUMS.REC.1395.181

Health conditions studied**1****Description of health condition studied**

Asthma

ICD-10 code

J45.0

ICD-10 code description

Predominantly allergic asthma Allergic: bronchitis NOS rhinitis with asthma Atopic asthma Extrinsic allergic asthma Hay fever with asthma

Primary outcomes**1****Description**

Asthma symptoms

Timepoint

Before and four weeks after intervention

Method of measurement

AQLQ and ACT Questionnaires

Secondary outcomes**1****Description**

Airway obstruction

Timepoint

Before and 4 weeks after intervention

Method of measurement

Spirometry

Intervention groups**1****Description**

Intervention group: Oral drug: Powder of almond gum and Plantago major seeds; Dose: 5 grams of the pack contains 3 grams of almond gum powder and 2 grams of Plantago major seed, every 8 hours, the duration of treatment (consumption): 4 weeks; How to use: Patients should dissolve the content of each pack in 150 ccs warm water and consume it after 30 minutes by maintaining an hour away from food.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ghaem Clinic

Full name of responsible person

Dr Farahzad Jabbari Azad, Allergy and Clinical Immunologist, Associate Professor

Street address

Special Clinic for Allergic diseases, Dr shariati Sq, Parastar St, Mashhad, Khorasan Razavi

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Razavi Khorasan
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9176699199
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+98 51 3840 0000
Email
Quaem.Medical.Center@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi, Research Vice Chancellor
Street address
Vice Chancellery for Research of Mashhad University of Medical Sciences, Golestan Crossroad, Daneshgah Ave, Mashhad, Iran
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vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Mashhad 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

Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Street address
Azadi Square, Mashhad University of Medical Sciences, School of Persian and Complementary Medicine
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kabolifm911@mums.ac.ir
Web page address
<http://tim.mums.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Anushiravani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
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Anushiravanim@mums.ac.ir
Web page address

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Masoumeh Sadat Kaboli Farshchi
Position
PhD Student of Traditional and Complementary

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Masoumeh Sadat Kaboli Farshchi
Position
PhD Student of Traditional and Complementary

Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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kabolifm911@mums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Patients' information belongs to the project implementer and Mashhad University of Medical Sciences

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The clinical study report will be shared in the form of a paper

When the data will become available and for how long

The clinical study report will be available 6 months after the publication of the results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

It is possible to use the results of the study for other research projects in collaboration with the execution research project and Mashhad University of Medical Sciences

From where data/document is obtainable

Applicants can contact the execution research project for this purpose Email address: Anushiravanim@mums.ac.ir Contact number 00989153218505

What processes are involved for a request to access data/document

The applicant can contact the execution research project 1 year after the publication of the results

Comments