Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Iran (Islamic Republic of)

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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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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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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

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 Medicine
Latest degree
Medical doctor
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Latest degree

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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