

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of combined herbal powder on the severity of symptoms (cough and dyspnea) and spirometry indexes in patients with asthma

Protocol summary

Study aim

Determining the effect of hybrid herbal powder on asthma symptoms and spirometric indices

Design

A clinical trial with a control group, a randomized, and triple blinds. The sample size is 51 in the experimental group and 51 in the control group

Settings and conduct

Consumption of combined herbal powder for one month in the experimental group and placebo powder in the control group. The study site is the clinic of Amir Al-Momenin Hospital in Arak. Patients are not aware of being in the experimental or control group.

Participants/Inclusion and exclusion criteria

Diagnosis of asthma, absence of other chronic obstructive pulmonary diseases, absence of respiratory infection in a recent month, no smoking and drugs

Intervention groups

Consumption of combined herbal powder in the intervention group and taking placebo powder in the control group

Main outcome variables

Asthma symptoms, spirometry indicators

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170501033751N4**

Registration date: **2022-03-19, 1400/12/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-19, 1400/12/28**

Update count: **0**

Registration date

2022-03-19, 1400/12/28

Registrant information

Name

rezvan ghafarzadegan

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3426 2226

Email address

rghafarzadegan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-11, 1400/12/20

Expected recruitment end date

2022-07-11, 1401/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combined herbal powder on the severity of symptoms (cough and dyspnea) and spirometry indexes in patients with asthma

Public title

The effect of combined herbal powder on asthmatic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

desire to participate in the study Age 18 to 65 years
Asthma at the diagnosis of a pulmonologist Absence of other respiratory diseases including bronchitis, chronic

obstructive pulmonary disease

Exclusion criteria:
 Evidence of respiratory infection in a recent month
 Recent exacerbation of clinical symptoms of asthma
 Unwanted side effects of herbal medicine
 Reluctance to cooperate in any of the stages of research
 Do not use herbal medicine as directed
 Herbal capsules provided)
 Change of standard drugs used by the patient during the study
 Perform surgery and general anesthesia during the study

Age
 From **18 years** old to **65 years** old

Gender
 Both

Phase
 2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
 Target sample size: **102**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Samples will be selected based on purpose and will be randomly assigned in two groups of intervention and control by balanced block randomization method.

Blinding (investigator's opinion)
 Triple blinded

Blinding description
 This study will be conducted in a three-blind design so that the participants, physician and treatment team of the respiratory clinic and the researcher based in the clinic will not have information about the allocation of individuals and the type of intervention applied to the participant. After a person who is eligible to participate in the study is introduced to the researcher by the clinic physician, the researcher informs the coordinating center of the relevant person by phone; In the coordinator center, the researcher is assigned based on the order of pre-determined codes and the envelope number that must be given to the person is notified. The number written on the envelopes is a random and irregular three-digit number. These numbers and codes for each person will be kept on confidential forms on the Coordination Center. The team based at the Coordination Center will not have direct contact with the participants and will not interfere in the collection of information and analysis of study data.

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Khomein School of Medical Sciences

Street address

Basij square

City

khomein

Province

Markazi

Postal code

3881857573

Approval date

2022-03-05, 1400/12/14

Ethics committee reference number

ir.khomein.rec.1400.020

Health conditions studied

1

Description of health condition studied

asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Asthma symptoms and spirometry indicators

Timepoint

Before the intervention and one month after the start of the use of herbal powder

Method of measurement

Using an asthma symptom questionnaire and a spirometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 500 mg mixed plant powder (containing 1000 mg of ocimum basilicum seeds. 1000 mg of plantago seeds • 1000 mg of plantago ovata forssk seeds • 1000 mg of Salvia macrosiphon seeds • 1000 mg of alyssum alyssoides seeds) orally at a rate of two sachets per day (to For a month). This powder is made by Ghaem Daroo Pharmaceutical Company.

Category

2**Description**

Control group: Consumption of sachets containing 5000 mg of toasted bread powder, which is similar in color and appearance to herbal powder, in the amount of two sachets per day orally (for one month). Placebo powder is made by Ghaem Daroo Pharmaceutical Company.

Category

Placebo

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

Amiralmomenin hospital in Arak

Full name of responsible person

rezvan ghafarzadegan

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Basij square

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

rezvan ghafarzadegan

Position

Academic instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

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Position

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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

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

All data is sharable when unrecognizable

When the data will become available and for how long

1400

To whom data/document is available

all researcher

Under which criteria data/document could be used

to related research

From where data/document is obtainable

khomein medical university. Deputy of Education and Research. Mr. Hamid Momeni. Phone number: 08646221534. Fax: 08646224143

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

Submit a written request via fax to receive documents to the Vice Chancellor for Education and Research of Khomein School of Medical Sciences and after a maximum of one month, receive information about the research

Comments