

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of the Honey and the Trigonella foenum-graceum L (fenugreek) seeds product effect on chronic obstructive pulmonary Disease: Double - Blinded Trial

Protocol summary

Study aim

Evaluation of the effect of honey and fenugreek seed product in the recovery and control of clinical symptoms (cough, sputum, shortness of breath) in patients with chronic obstructive pulmonary disease. □ Evaluation of the effect of honey and fenugreek seed product on pulmonary function tests (spirometry) in patients with chronic obstructive pulmonary disease.

Design

The clinical trial work has a control group, with parallel, double-blind, randomized groups on 81 patients, and the type of treatment is allocated to patients in a simple random manner with the help of power G software. ,

Settings and conduct

After the homogenization of the groups in terms of intervening factors, the manufactured drugs including: honey syrup and fenugreek seeds, honey syrup and placebo will be coded. One group will receive honey syrup, the next group will receive a combination of fenugreek and honey, and the third group will receive a placebo. For the double-blindness of the study, the doctor, student, and patient will not know about the coding. And the codes are kept with the analyzer and the code given to each patient will be recorded on the patient information registration form

Participants/Inclusion and exclusion criteria

Patients are randomly selected from those who refer to Tabriz University of Medical Sciences (campus clinic) by a lung specialist with a diagnosis of COPD, who have stable conditions and do not have underlying diseases, age range 30 to 60 years.

Intervention groups

Patients will be divided into three groups of 27 people and one group will receive placebo as a control group, the second group will receive honey syrup and the third group will receive a combination of honey and fenugreek products for 4 weeks.

Main outcome variables

Cough confusion Activity shortness of breathg
Spirometry

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221105056400N1**

Registration date: **2022-12-04, 1401/09/13**

Registration timing: **prospective**

Last update: **2022-12-04, 1401/09/13**

Update count: **0**

Registration date

2022-12-04, 1401/09/13

Registrant information

Name

Parisa Ghaffari babil oliaie

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-29, 1401/10/08

Expected recruitment end date

2023-08-30, 1402/06/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the Honey and the Trigonella foenum-graceum L (fenugreek) seeds product effect on chronic obstructive pulmonary Disease: Double – Blinded Trial

Public title

Effect of Honey and Trigonella foenum of copd

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Moderate COPD Deasese diagnosed with Pulmonologist Deasese with stable condition Deasese age 30-60 deasese with self consent

Exclusion criteria:

Deasese with Diabet Melitos Deasese with Alergy Honey and Trigonella foenum Deasese with Pregnancy or Lactation Deasese with sever COPD Deasese with Underlying deasese such as CF.Heart Failre.Pulmonal Amboly.Ressistant HTN Deasese with Pulmonal cancer or other cansers

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **81**

More than 1 sample in each individual

Number of samples in each individual: **27**

Deasese division to 27 patient

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomizationDue to the double-blindness of the study, the doctor, student, and patient will not know about the coding. And the codes are kept with the analyzer and the code given to each patient will be recorded on the patient information registration for

Blinding (investigator's opinion)

Double blinded

Blinding description

Direction of Double blind study, doctor medical, student and patient dont know of cods.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

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Street address

Blvd. of Ostad Saboti, Zanjan University of Medical Sciences

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Zanjan

Province

Zanjan

Postal code

4513956184

Approval date

2022-11-02, 1401/08/11

Ethics committee reference number

1401.220

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

Cronic Obstructive Pulmonary Deasese

ICD-10 code

j44.1

ICD-10 code description

j44.1

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

Disease score based on reliability of chronic obstructive pulmonary disease(cat)

Timepoint

Clinical examination and reliability of the disease at the beginning of the study (before intervention) 7, 14 and 21 and after consuming fenugreek and honey syrup at the end of the stud

Method of measurement

Reliability questionnaire of chronic obstructive pulmonary disease(cat) and spirometry

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

The secondary outcome is the improvement of activity dyspnea and energy level and sleep

Timepoint

Before starting the study, on the 7th, 14th, 21st, and then, take fenugreek and honey syrup

Method of measurement

Reliability standard guidelines for chronic obstructive pulmonary diseases (cat)

2

Description

The secondary outcome is the improvement of activity dyspnea and energy level and sleep

Timepoint

Before starting the study, on the 7th, 14th, 21st, and then, take fenugreek and honey syrup

Method of measurement

Reliability standard guidelines for chronic obstructive pulmonary diseases (cat)

Intervention groups

1

Description

Intervention group:: Patients will be divided into three groups of 27 people and one group will receive placebo and the second group will receive honey syrup and the third group will receive a combination of honey and fenugreek products for 4 weeks. Fenugreek syrup products and Honey and honey syrup will be prepared at the Faculty of Pharmacy of Zanjan University of Medical Sciences and after checking and verifying the quality of herbal ingredients and honey and chemical and microbial stability, the products will be prescribed to patients. The product of fenugreek and honey will be standardized by checking the amount of total saponin based on the active substance Diosgenin. Patients are given a daily amount of syrup containing the extract obtained from 5 grams of fenugreek powder in 2 A divided dose will be prescribed. According to previous studies, the amount of honey will be 40 grams of honey per 100 ml in honey and fenugreek syrup, and honey and placebo syrup will be based on 40 grams of sweetener per 100 ml.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Tabriz University of Medical Sciences (Pardis clinic).

Full name of responsible person

Dr Mehdi Nadiri. Pulmonologist

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New Pastor St.,Pardis Building, 2nd floor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Samad Nadri

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Technology Deputy

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Grant name

Grant code / Reference number

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

No

Title of funding source

Research and Technology of Zanjan University of Medical
Sciences (Dr. Samad Nedri)

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

Zanjan University of Medical Sciences

Full name of responsible person

Dr Parisa Jafari

Position

Traditional medicine doctor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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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

Yes - There is a plan to make this available

Title and more details about the data/document

All data cannot be shared after de-identifying individuals, but part of the information related to the main outcome can be shared

When the data will become available and for how long

Start accessing results 6 months later

To whom data/document is available

Researchers working in academic and scientific institutions and people in the pharmaceutical industry

Under which criteria data/document could be used

in order to study students and researchers, especially in the field of herbal medicines and traditional pharmaceuticals, under research-oriented conditions and to continue studies in the field of traditional medicine and other valid fields in the field of health and medicine.

From where data/document is obtainable

My email, mobile number

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

Six months later, the article was published

Comments