Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the therapeutic effect of polyphenols derived from Ficus carica in COPD: a randomized placebo-controlled

Protocol summary

Study aim
Investigating the therapeutic effect of polyphenols derived from Ficus carica in COPD: a randomized placebo-controlled clinical trial

Design
This is a single-center, Phase III, randomized, placebo-controlled trial with 60 COPD participants (30 herbal drug, 30 placebo). The primary endpoint is a clinically significant change in CAT questionnaire scores (binary outcome), assessed and FEV1 with 1:1 randomization.

Settings and conduct
The drugs and placebo bottles are coded by a person not involved in the trial. the codes will be used for recording the outcomes. After gathering the outcome data the codes and data will be analyzed by PI.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with moderate COPD (FEV1%<70%predicted), Ex smokers and not current smokers. Exclusion criteria: patient with congestive heart failure (CHF), asthma, and restrictive lung diseases. Patients with any other types of chronic diseases including kidney, liver, and heart.

Intervention groups
Control group (N = 30), GOLD treatment protocol of COPD plus placebo Intervention group (N = 30), GOLD treatment protocol of COPD plus Ficus carica fruit extraction pills

Main outcome variables
CAT questionary scores, FEV1

General information

Reason for update

Acronym
FICCOPD

IRCT registration information
IRCT registration number: **IRCT20200818048444N5**
Registration date: **2025-09-24, 1404/07/02**
Registration timing: **registered_while_recruiting**
Last update: **2025-09-24, 1404/07/02**
Update count: **0**

Registration date
2025-09-24, 1404/07/02

Registrant information

Name
Khalil Ansarin

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3337 8093

Email address
dr.ansarin@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2026-09-22, 1405/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the therapeutic effect of polyphenols derived from Ficus carica in COPD: a randomized placebo-controlled

Public title
Investigating the therapeutic effect of fig extract in COPD

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with mild or moderate COPD (FEV1/FVC<70% and FEV1<80%predicted and > 45% predicted) no significant bronchodilator response as defined by ATS criteria All patients should be Ex-smokers who have not smoked within the past 4 months

Exclusion criteria:

patient with congestive heart failure (CHF) asthma restrictive lung diseases patients with any other types of chronic diseases including kidney, liver, and heart disease

Age

From **18 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The pills and placebo boxes are coded by an investigator not involved in the research, and the boxes are then distributed to participants by another investigator who is unaware of whether they contain the placebo or the intervention. So, the patients receive randomized treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

The pills and placebo boxes are coded by an investigator not involved in the research, and the boxes are then distributed to participants by another investigator who is unaware of whether they contain the placebo or the intervention. after gathering the data patients with their corresponding treatment code, the code table will be obtained from the non-involved investigator by the principal investigator to be analyzed by the analyzer.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz medical university

Street address

Tanhayii, St, Pashmineh, Tuberculosis and lung disease research center

City

Tabriz

Province

East Azarbaijan

Postal code

51656658112

Approval date

2025-03-10, 1403/12/20

Ethics committee reference number

IR.TBZMED.REC.1403.1059

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description

reduction in CAT score

Timepoint

before intervention and 2, 4 , 6 weeks after intervention

Method of measurement

questionnaire- statistical analysis, HPLC and Enzyme assay

Secondary outcomes

1

Description

Oxidative stress biomarkers in EBC

Timepoint

4 weeks

Method of measurement

special kits

Intervention groups

1

Description

Control group:

Category

Placebo

2

Description

Intervention group: The active pharmaceutical

ingredients were prepared by the pharmacy colleagues involved in this project at the College of Pharmacy as follows:Pure, dried fig fruit (Ficus carica) was purchased from the market. It was ground using a laboratory herbal grinder, model XJT-DFG500g (Guangzhou Xinjiate Machinery Equipment Co., Ltd., Guangdong, China), to produce a fine powder. One hundred grams of the fruit powder were steeped in one liter of a hydroalcoholic solvent (70% ethanol in distilled water). This process involved repeated maceration under vigorous shaking at room temperature for 24 hours. The entire mixture was then filtered through Whatman filter paper, and the filtrate containing the extract was concentrated using a rotary evaporator (Laborota 4002, Heidolph, Germany) to separate the solvent. The total extract was dried using an air dryer.The extract prepared by this method was then formulated into soft gels by Zahravi Pharmaceutical Company. Each gelatin capsule contained 675 mg of the extract. For the participants, a daily dosage of two capsules, three times a day (totaling 4 grams of fig extract per day), will be administered with meals for a period of three months.The size and color of the placebo capsules were designed to be similar to the drug-containing capsules; however, they were filled with a filler material (microcrystalline cellulose).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir Amiri Sadeghan

Full name of responsible person
Khalil Ansarin

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Tanhayie, St, Pashmineh, Tuberculosis and lung disease research center

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dr.ansarin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran National Science Foundation

Full name of responsible person
Dr. Khalil Ansarin

Street address
Tanhayii, St, Pashmineh, Tuberculosis and lung disease research center

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Grant name

Grant code / Reference number
4021176

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Iran National Science Foundation

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

2

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Khalil Ansarin

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Amirisadeghan@Tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Iran National Science Foundation

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

Tabriz University of Medical Sciences

Full name of responsible person

Amir Amiri Sadeghan

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Medical Nanotechnology

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Nanotechnology

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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 collected deidentified IPD

When the data will become available and for how long

after acceptance for publication in an appropriate journal

To whom data/document is available

we will participate in open-data journals who provides a link for raw data

Under which criteria data/document could be used

we will obey the the journal ethics on sharing data with third party

From where data/document is obtainable

from the link journal will provide

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

not a specific process

Comments