

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 questionnaire 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

**recruiting**

##### 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

**Street address**

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Iran National Science Foundation

**Full name of responsible person**

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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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**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  
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Consultant  
**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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