# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Evaluation the effects of Cordia myxa syrup on the symptoms of Chronic bronchitis patients.

## Protocol summary

**Study aim**
Determination and comparison of the effects of *Cordia myxa* syrup on the symptoms of patients with chronic bronchitis in the intervention and control groups.

**Design**
A Phase 2, randomized, double-blind, parallel-group, controlled clinical trial involving 100 patients. The Excel `rand` function was used for randomization.

**Settings and conduct**
The procedure was explained above. It is performed at the specialized pulmonary clinic in the city of Yazd.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: 1- Chronic sputum production and a decrease in FEV1 to less than 80% for at least 3 months over two consecutive years 2- 30% < FEV1 < 80% 3- Age 40 to 75 years 4- Diagnosis confirmed by a pulmonologist 5- No symptoms of the common cold or pneumonia within the past month 6- No hospitalization within the past month 7- No use of other expectorants or mucolytics

**Intervention groups**
Eligible patients will be randomly selected and allocated to the drug or placebo group using a double-blind design, with balanced representation by sex and disease severity. All patients will receive standard COPD treatment and take the study medication three times daily, one tablespoon per dose. Clinical symptoms (cough, sputum, dyspnea, sleep quality, and daily functioning) will be assessed before treatment and after one month using the BSS, SGRQ, and CAT scales. Treatment adherence and adverse effects will be monitored by telephone. Drug safety will be evaluated, and data will be analyzed using SPSS version 24.

**Main outcome variables**
Cough Phlegm Shortness of breath Nighttime sleep Daily functioning

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20260815070648N1**
Registration date: **2026-10-11, 1405/07/19**
Registration timing: **retrospective**

Last update: **2026-10-11, 1405/07/19**
Update count: **0**

**Registration date**
2026-10-11, 1405/07/19

**Registrant information**

**Name**
Erfan Nasr azadani

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2026-04-21, 1405/02/01

**Expected recruitment end date**
2026-08-16, 1405/05/25

**Actual recruitment start date**
2026-04-21, 1405/02/01

**Actual recruitment end date**
2026-08-16, 1405/05/25

**Trial completion date**
empty

**Scientific title**

Evaluation the effects of Cordia myxa syrup on the symptoms of Chronic bronchitis patients.

**Public title**

"Cordia myxa syrup in chronic bronchitis"

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Chronic sputum production and a reduction in FEV1 to less than 80% for at least 3 months over two consecutive years. Age 40 to 75 years FEV1 below 80% and above 30% The individual's condition must be confirmed by a pulmonologist. Must not have had symptoms of a cold or pneumonia over the past month. Must not have been hospitalized within the past month. Avoid using other expectorants and mucolytics.

**Exclusion criteria:**

FEV1 more than 80% or other chronic lung diseases such as bronchiectasis, tuberculosis, silicosis, etc. Has had symptoms of a cold or pneumonia over the past month. Has been hospitalized within the past month Heart disease

**Age**

From **40 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**

Target sample size: **40**

Actual sample size reached: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Initially, a syrup containing the Cordia myxa herbal preparation was manufactured by a knowledge-based company. The herbal syrup and placebo were then prepared with identical formulation characteristics, volume, appearance, and packaging and were coded as A and B by the manufacturer. The code key was retained by the manufacturer, and the physician, participants, and outcome assessor were unaware of which code corresponded to the active treatment or placebo. After screening for the eligibility criteria and obtaining informed consent, eligible participants were randomly allocated to the two study groups in a 1:1 ratio. A computer-generated random allocation sequence was prepared before the initiation of participant recruitment. For each eligible participant, one of the two treatment codes (A or B) was assigned according to the predetermined random sequence. Thus, allocation was not based on the participant's clinical characteristics, age, sex, order of recruitment, or physician judgment, and each eligible participant had an equal probability of being assigned to either the Cordia myxa or placebo group. Following random allocation, the medication package corresponding to the assigned code was provided to the participant without revealing whether it contained the active Cordia myxa syrup or placebo. Because the two preparations were indistinguishable in appearance and packaging, neither the participants nor the treating physician could predict or identify the treatment assignment. Clinical symptoms and study outcomes were assessed without knowledge of treatment allocation. The code key remained confidential throughout participant recruitment, treatment, and outcome assessment and was unblinded only after completion of data collection and evaluation.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

First, a syrup based on the *Cordia myxa* plant is prepared by a knowledge-based company; it is then packaged alongside a placebo in identical containers and coded as "A" and "B." The medication and placebo packages are indistinguishable, bearing only the manufacturer's "A" and "B" codes, ensuring that neither the physician nor the patient knows which contains the active drug and which the placebo. Subsequently, patients meeting the specified criteria are selected at random, and the treatments are administered randomly without the patient or physician knowing whether the substance is the drug or the placebo.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

**Street address**

Bahonar Square, beginning of South Shahid Sadoughi [Street]

**City**

Yazd

**Province**

Yazd

**Postal code**

4513779399

**Approval date**

2025-12-15, 1404/09/24

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1404.250

## 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**
Age, Sex, Weight, BMI, Smoking, Substance Dependence, FEV1
**Timepoint**
One month after taking the medication
**Method of measurement**
BSS, SGRQ, and CAT criteria

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: First, a syrup based on the *Cordia myxa* plant is prepared by a knowledge-based company; the syrup and a placebo are then packaged identically and coded as "A" and "B." The packages containing the medication and the placebo are indistinguishable, bearing only the "A" and "B" codes assigned by the manufacturer, ensuring that neither the physician nor the patient knows which is the active drug and which is the placebo. Subsequently, patients meeting the specified criteria are selected at random and assigned the treatment—either the medication or the placebo—in a randomized manner, without the patient or physician being aware of the assignment. All patients also receive standard, primary COPD treatment as prescribed by a pulmonologist. The patient is required to take the medication three times daily, with a dosage of one tablespoon each time. Prior to prescribing the medication, the patient's symptoms (including cough, sputum production, and shortness of breath) and their status—assessed using BSS, SGRQ, and CAT criteria—are evaluated and recorded. A follow-up assessment of symptoms is conducted one month later during the subsequent visit. Additionally, adherence to the medication regimen and any potential side effects are monitored via telephone follow-ups.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Baghaei-Pour Clinic, Yazd
**Full name of responsible person**
Erfan Nasr azadani
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Riazi Square, Ibn-e Sina Street, next to Shahid Sadoughi Hospital
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## Sponsors / Funding sources

**1**

**Sponsor**
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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**
Yazd 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**
Yazd University of Medical Sciences

**Full name of responsible person**
Dr. Fatemeh-Sadat Aghaei

**Position**
Pulmonologist (Pulmonary Sub-specialist)

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Internal Medicine

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## Person responsible for scientific inquiries

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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**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
No - There is not a plan to make this available

**Title and more details about the data/document**
Information regarding the study results, the drug's efficacy (or lack thereof), instructions for use, and indications.

**When the data will become available and for how long**
Once the results are confirmed—likely starting in early 1406...

**To whom data/document is available**
All physicians, students, and individuals associated with the medical field.

**Under which criteria data/document could be used**
In order to provide better treatment for patients, and under conditions that meet at least the minimum financial requirements for the future...

**From where data/document is obtainable**
The manufacturing company and the individuals involved in the development of this drug.

**What processes are involved for a request to access data/document**
Based on clinical indications and following physician approval, via an online or paper prescription.

**Comments**