Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 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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+98 35 3820 3412
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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
Name of organization / entity
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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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Name of organization / entity
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Position
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Person responsible for updating data

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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