

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of Montelukast drug on pulmonary function and clinical symptoms of patients with moderate to severe COPD

Protocol summary

Study aim

Comparison of the mean difference in FEV1
Comparison of the mean difference in FVC
Comparison of the mean difference in FEF25-75%
Comparison of the mean difference in FEV₁/FVC ratio
Comparison of the number of exacerbation episodes
Comparison of clinical improvement in dyspnea based on the modified MMRC questionnaire
Comparison of clinical improvement in dyspnea based on the COPD Assessment Test (CAT)

Design

Randomized triple-blind phase 2 clinical trial, parallel-group design, including one intervention group (Montelukast 10 mg daily for two months) and one placebo group (one tablet daily for two months). Sixty-two patients will be randomized using balanced block randomization (using online software).

Settings and conduct

This study will be conducted at Imam Khomeini Hospital in Ahvaz and in related pulmonary specialists' offices. Blinding is maintained for all study stakeholders, including the patient, prescriber, outcome assessor, data analyst, investigator, and oversight committee members, due to the use of placebo. The data analyst will perform analyses based on two anonymized groups labeled A and B.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 40 to 70 years diagnosed with moderate to severe COPD, clinically stable over the past three months, with no history of hospitalization in the past six months, and who have completed a written informed consent form. Exclusion criteria: Patients with advanced cardiovascular disease; autoimmune or inflammatory rheumatologic disorders; uncontrolled hypertension; progressive kidney disease; and hypersensitivity to Montelukast.

Intervention groups

Intervention: Montelukast (Zahravi Pharmaceutical Company) one 10 mg tablet daily for two months.
Control: A placebo daily for two months. Jundishapur

Faculty of Pharmacy manufactures the placebo.

Main outcome variables

Forced expiratory volume, Forced vital capacity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251108067917N1**

Registration date: **2025-11-20, 1404/08/29**

Registration timing: **registered_while_recruiting**

Last update: **2025-11-20, 1404/08/29**

Update count: **0**

Registration date

2025-11-20, 1404/08/29

Registrant information

Name

Mohsen Hajiani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-16, 1404/08/25

Expected recruitment end date

2026-04-14, 1405/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of Montelukast drug on pulmonary function and clinical symptoms of patients with moderate to severe COPD

Public title
Study of Montelukast in COPD

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 40 to 70 years Diagnosed with moderate to severe COPD Clinically stable over the past three months No history of hospitalization in the past six months Signed written informed consent
Exclusion criteria:
Patients with advanced cardiovascular disease, including EF less than 40% Rheumatologic diseases Uncontrolled hypertension Progressive kidney disease with a glomerular filtration rate (GFR) less than 30 mL/min Hypersensitivity to Montelukast

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method and description: Balanced block randomization. Unit of randomization: Individual participant. Stratification layers (if stratified randomization is used): Not applicable. Randomization tool: The sequence of drug and placebo allocation is determined using statistical software and predefined block sizes. Random sequence generation: Drug and placebo packages are identical in appearance and labeled with sequential numbers according to the randomization list. These are provided to the designated unit/person responsible for dispensing the intervention, to be distributed in order to participants enrolled in the study. Allocation concealment: The randomization list is prepared in duplicate and kept by an individual not involved in the study and not present at the study site. During data analysis, only two groups labeled A and B are provided to the analyst. The identity of the drug and placebo groups is revealed only after completion of the

analysis and summary of results.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Since the placebo in this study is manufactured and provided by the producing company, there is no visual difference between what is given to the dispenser and the patient. Therefore, there is no way for the outcome assessor, data analyst, or even members of the safety and data monitoring committee to identify the type of intervention. All parties remain blinded to whether the patient receives the active drug or the placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Ahvaz Jundishapour University of Medical Sciences

Street address
Ground Floor, Office of Research and Technology Ahvaz Jundishapur University of Medical Sciences University Campus

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اهواز

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Khuzestan

Postal code
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Approval date
2025-07-26, 1404/05/04

Ethics committee reference number
IR.AJUMS.REC.1404.232

Health conditions studied

1

Description of health condition studied
chronic obstructive pulmonary disease

ICD-10 code
J44

ICD-10 code description
Other chronic obstructive pulmonary disease

Primary outcomes

1

Description
FEV1

Timepoint

One day before the intervention, and at two and four months after the start of the intervention

Method of measurement

Spirometer

2

Description

FVC

Timepoint

One day before the intervention, and at two and four months after the start of the intervention

Method of measurement

Spirometer

Secondary outcomes

1

Description

FEF25-75%

Timepoint

One day before the intervention, and at two and four months after the start of the intervention

Method of measurement

Spirometer

2

Description

FEV1/FVC ratio

Timepoint

One day before the intervention, and at two and four months after the start of the intervention

Method of measurement

Spirometer

3

Description

The number of exacerbation episodes

Timepoint

Two and four months after the start of the intervention

Method of measurement

History taking

4

Description

Clinical improvement in dyspnea

Timepoint

One day before the intervention, and at two and four months after the start of the intervention

Method of measurement

The modified Medical Research Council questionnaire

5

Description

Clinical improvement in dyspnea

Timepoint

One day before the intervention, and at two and four

months after the start of the intervention

Method of measurement

The chronic obstructive pulmonary disease assessment test

Intervention groups

1

Description

Intervention group: Receives Montelukast, manufactured by Zahravi Pharmaceutical Company, at a dose of one 10 mg oral tablet daily for two months.

Category

Treatment - Drugs

2

Description

Control group: Receives placebo for two months. The placebo is manufactured by Jundishapur Faculty of Pharmacy.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Ahvaz, Pulmonology Department

Full name of responsible person

Seyed Hamid Borsi

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Azadegan Street Imam Khomeini Educational and Medical Center,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Abdollah Rafiei

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohsen Hajiani

Position

Non-faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available