# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 $FEV_1$/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)
**Phone**
+98 21 2268 9668
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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% Rheumatologc 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

**City**

اهواز

**Province**

Khouzestan

**Postal code**

1579461357

**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 StreetImam Khomeini Educational and Medical Center,
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## Sponsors / Funding sources

**1**

**Sponsor**
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itc@ajums.ac.ir

**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
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Mohsen Hajiani
**Position**
Non-faculty specialist physician
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## Person responsible for updating data

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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