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 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
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Iran (Islamic Republic of)
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+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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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
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
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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