Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Blood Inflammatory Markers and Their Comparison with Exercise Capacity Indices in Patients with Chronic Obstructive Pulmonary Disease Following Short-Term Pulmonary Rehabilitation

Protocol summary

Study aim

Evaluation of Blood Inflammatory Markers and Their Comparison with Exercise Capacity Indices in Patients with Chronic Obstructive Pulmonary Disease Following Short-Term Pulmonary Rehabilitation

Design

In this study, which will be conducted in phase III of a clinical trial, a total of 206 patients will be enrolled according to the inclusion and exclusion criteria. After obtaining written informed consent, they will be randomly assigned (using permuted block randomization) in a single-blind manner into two groups: intervention and control.

Settings and conduct

This study is a phase III clinical trial conducted in a randomized (using permuted block randomization) and single-blind manner on patients with chronic obstructive pulmonary disease (COPD) who are referred to Masih Daneshvari Hospital.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study include a definite diagnosis of chronic obstructive pulmonary disease based on the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria, age above 18 years, stability of the patient's clinical condition at the time of entry into the study, and the ability to perform functional tests. Patients who develop acute respiratory symptoms or infection during the rehabilitation period, patients with a history of exacerbation, or those who are unwilling to cooperate will be excluded from the study.

Intervention groups

In the control group, patients receive respiratory physiotherapy and bedside exercises. In the intervention group, in addition to active care, training in caregiving techniques, and bedside physiotherapy, patients receive the full rehabilitation program and participate in a pulmonary rehabilitation program.

Main outcome variables

Platelet-to-lymphocyte ratio, erythrocyte sedimentation rate, neutrophil-to-lymphocyte ratio

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210813052172N4**
Registration date: **2026-05-05, 1405/02/15**
Registration timing: **prospective**

Last update: **2026-05-05, 1405/02/15**
Update count: **0**

Registration date

2026-05-05, 1405/02/15

Registrant information

Name

Masoumeh ZoghAli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3662 4225

Email address

masoumezoghali@sbmu.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2027-03-21, 1406/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Blood Inflammatory Markers and Their Comparison with Exercise Capacity Indices in Patients with Chronic Obstructive Pulmonary Disease Following Short-Term Pulmonary Rehabilitation

Public title
Assessment of the Effect of Pulmonary Rehabilitation in Patients with Chronic Obstructive Pulmonary Disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of COPD based on GOLD criteria Age over 18 years Stability of the patient’s clinical condition at the time of study entry Ability to perform functional tests
Exclusion criteria:
Exacerbation of the disease within the past two weeks Acute respiratory symptoms or infection during pulmonary rehabilitation period Incomplete training sessions for any reason Lack of willingness to cooperate in performing functional tests or completing questionnaires
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **206**
Randomization (investigator's opinion)
Randomized
Randomization description
The method used is permuted block randomization. For this purpose, two treatment groups, A and B, are defined in blocks as AB and BA. Then, numbers from a random table in the range 0 to 9 are considered. Numbers 0 to 4 are assigned to block AB, and numbers 5 to 9 are assigned to block BA. Random numbers are then selected from the table. If the number 0 appears, it corresponds to block AB, and therefore two individuals enter this block, such that the first individual receives treatment A and the second individual receives treatment B. In the same way, the treatment groups for the remaining participants are determined. Although in this method the number of observations in both groups will be equal, because of the small block sizes, there is a high probability that the person conducting the study may predict the treatment group assignment. To solve this problem, the randomization list is prepared before the start of the study by a blinded individual who is not part of the treatment team. Additionally, the block sizes will be increased.
Blinding (investigator's opinion)
Single blinded
Blinding description
Given the nature of the study, which involves pulmonary rehabilitation, blinding of participants and therapists is not feasible, as patients will be aware of the type of treatment they receive. To minimize potential bias, the outcome assessor and the statistical data analyst will be blinded to group allocation. For this purpose, patient information will be provided to the outcome assessor and the statistical analyst in a coded format, and they will not have access to information regarding the type of intervention. Data analysis will be conducted solely based on the assigned codes
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of School of Medicine, Shahid Beheshti University of Medical Sciences
Street address
Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1956944413
Approval date
2026-02-17, 1404/11/28
Ethics committee reference number
IR.SBMU.MSP.REC.1404.763

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
Neutrophil-to-lymphocyte ratio
Timepoint
Before starting pulmonary rehabilitation and after completing 10 days of pulmonary rehabilitation
Method of measurement
Complete Blood Count

2

Description
Platelet-to-lymphocyte ratio
Timepoint
Before starting pulmonary rehabilitation and after completing 10 days of pulmonary rehabilitation
Method of measurement
Complete Blood Count

3

Description
Erythrocyte sedimentation
Timepoint
Before starting pulmonary rehabilitation and after completing 10 days of pulmonary rehabilitation
Method of measurement
Complete Blood Count

Secondary outcomes

1

Description
Exercise capacity
Timepoint
Before initiation pulmonary rehabilitation and after 10 days pulmonary rehabilitation
Method of measurement
Six minute walk test

2

Description
Strength and endurance of the lower limb muscles
Timepoint
Before starting pulmonary rehabilitation and after completing 10 days of pulmonary rehabilitation
Method of measurement
Sit to stand test

3

Description
Dyspnea
Timepoint
Before starting pulmonary rehabilitation and after completing 10 days of pulmonary rehabilitation
Method of measurement
Borg scale questionnaire

4

Description
Fatigue
Timepoint
Before starting pulmonary rehabilitation and after completing 10 days of pulmonary rehabilitation
Method of measurement
Borg scale questionnaire

5

Description
Quality of life
Timepoint
Before starting pulmonary rehabilitation and after completing 10 days of pulmonary rehabilitation
Method of measurement
St. George's Questionnaires and Chronic Obstructive Pulmonary Disease Assessment Test (CAT)

Intervention groups

1

Description
Intervention group: In addition to active care, patients receive education on care techniques and bedside physiotherapy, undergo a full rehabilitation program, and participate in a structured 10-session pulmonary rehabilitation program.
Category
Rehabilitation

2

Description
Control group: Patients receive active care and only basic respiratory education and care techniques (teaching sitting posture, simple diaphragmatic breathing, pursed-lip breathing), education and counseling (medication management, breathlessness management, teaching breathlessness control), and respiratory physiotherapy and bedside exercises (range-of-motion exercises and strengthening of respiratory muscles in a seated position in bed, isometric exercises, and prescribed exercises to maintain daily activities).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Masoumeh Zoghali
Street address
Masih Daneshvari Hospital, Daarabad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Maryam Sadat Mirenayat
Position
Associate professor
Latest degree
Subspecialist
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available