Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of adding pulmonary rehabilitation to respiratory physiotherapy in patients with COPD exacerbation, referring to Masih Daneshvari Hospital

Protocol summary

Study aim

Investigating the effect of adding the pulmonary rehabilitation to respiratory physiotherapy in patients with COPD exacerbation referring to Masih Daneshvari Hospital

Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 82 patients, using a random number table for randomization.

Settings and conduct

The present study is a clinical trial on patients with chronic obstructive pulmonary disease (COPD) exacerbation referred to Masih Daneshvari Hospital in Tehran. In the control group, patients perform breathing exercises along with upper limb stretching. In the intervention group, in addition to the control group exercises, patients perform aerobic exercise on a stationary bike or treadmill. Then, they perform strengthening exercises on the muscles of the upper and lower limbs.

Participants/Inclusion and exclusion criteria

Inclusion criteria included COPD grade 3 and higher (FEV1% predicted"30-49 and ˂30, post bronchodilator FEV1/FVC˂0.7), no comorbidities, no separate medication outside the prescribed line of therapy, patients undergoing oxygen therapy and line of therapy including antibiotics, corticosteroids, bronchodilators (spray) at the same dose, and exclusion criteria included acute cardiac problems, pneumothorax, embolism, musculoskeletal problems, severe distress, and the patient's inability to perform tests.

Intervention groups

In the control group, the patient is initially taught breathing exercises and stretching exercises on the bed by a specialist physiotherapist. In the intervention group, in addition to respiratory physiotherapy, the patient performs an aerobic exercise program on a stationary bike or treadmill, followed by light strengthening exercises.

Main outcome variables

Sit-to-stand test results, 6-minute walk test distance, quality of life, results of the hospital anxiety and depression questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240413061474N3**
Registration date: **2025-08-25, 1404/06/03**
Registration timing: **prospective**

Last update: **2025-08-25, 1404/06/03**
Update count: **0**

Registration date

2025-08-25, 1404/06/03

Registrant information

Name

Abouzar Mojibian

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2610 9946

Email address

dr.a.mojibian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2026-04-21, 1405/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of adding pulmonary rehabilitation to respiratory physiotherapy in patients with COPD exacerbation, referring to Masih Daneshvari Hospital

Public title
Investigating the effect of pulmonary rehabilitation along with respiratory physiotherapy in COPD exacerbation patients

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
post bronchodilator FEV1/FVC less than 0.7 Predicted FEV1 percentage 30-49 and less than 30(Edited)Restore original Absence of comorbidities Non-receipt of a separate medication outside the prescribed treatment line Patients receiving oxygen therapy Treatment includes antibiotics, corticosteroids, and bronchodilators (spray) at the same dose.

Exclusion criteria:
Acute cardiac problems pneumothorax embolism musculoskeletal problems severe distress patient inability to perform tests

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **82**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, a simple randomization method is used with the help of a random number table. For this purpose, two groups are named as A and B. We choose one of the rows of the random number table at will, and the numbers in each row will be between 0 and 9. We assign the numbers 0-4 to treatment A and the numbers 5-9 to treatment B.

Blinding (investigator's opinion)
Single blinded

Blinding description
The clinical outcome assessor will not have access to patient grouping and will remain blinded throughout the study. Patients and therapists will not be blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the School of Medicine, Shahid Beheshti University of Medical Sciences

Street address
Darabad, Masih Daneshvari Hospital

City
Tehran

Province
Tehran

Postal code
1956944413

Approval date
2025-07-29, 1404/05/07

Ethics committee reference number
IR.SBMU.MSP.REC.1404.262

Health conditions studied

1

Description of health condition studied
Chronic obstructive pulmonary disease

ICD-10 code
J44.1

ICD-10 code description
Chronic obstructive pulmonary disease with (acute) exacerbation

Primary outcomes

1

Description
6-minute walk test distance

Timepoint
Before and after rehabilitation

Method of measurement
6-minute walk test

2

Description
Number of sit-ups in 30 seconds

Timepoint
Before and after rehabilitation

Method of measurement
Sit to stand test

3

Description
Dyspnea
Timepoint
Before and after rehabilitation
Method of measurement
Modified Borg Scale

Secondary outcomes

1

Description
Quality of life
Timepoint
Before and after rehabilitation
Method of measurement
St. George Questionnaire, Chronic Respiratory Disease Questionnaire, Activities of Daily Living Questionnaire

2

Description
Anxiety and depression
Timepoint
Before and after rehabilitation
Method of measurement
Hospital anxiety and depression scale

Intervention groups

1

Description
Intervention group: Initially, the patient is taught breathing exercises and stretching exercises on the bed by a specialist physiotherapist. Breathing exercises include pursed lip breathing with diaphragmatic breathing and deep breathing with upper limb stretching. Then, an aerobic exercise program and strengthening exercises are performed.
Category
Rehabilitation

2

Description
Control group: Patients perform breathing exercises, diaphragmatic breathing, and deep breathing along with upper limb stretching.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Mina Fereydouni
Street address
Masih Daneshvari Hospital, Darabad
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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
Street address
Yemen St, Shahid Chamran Highway
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Province
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Postal code
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Phone
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Email
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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
Mohsen Abedi
Position

Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Position
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Internal Medicine

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Person responsible for updating data

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Researcher

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Master

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Biotechnology

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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