

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 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% predicted³⁰⁻⁴⁹ 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 Mojbibian

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2610 9946

Email address

dr.a.mojbiban@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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zahirireyhane@gmail.com

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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1983969411

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Assistant professor

Latest degree

Subspecialist

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Person responsible for updating data

Contact

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Reyhaneh Zahiri

Position

Researcher

Latest degree

Master

Other areas of specialty/work

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