

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of aerobic exercises on antioxidant indices of pulmonary hypertension (PH) patients with chronic obstructive pulmonary disease (COPD)

Protocol summary

Study aim

Investigating the effect of aerobic exercises on antioxidant indices of pulmonary hypertension (PH) patients with chronic obstructive pulmonary disease (COPD)

Design

A double-blind, randomized, parallel-groups, controlled, phase 3 clinical trial in 126 patients. A table of random numbers was used for randomization.

Settings and conduct

The present study is a clinical trial on pulmonary hypertension (PH) patients with chronic obstructive pulmonary disease (COPD) referring to Masih Daneshvari Hospital in Tehran. Patients are randomly divided into two groups. In the intervention group, patients perform physiotherapy exercises, including diaphragmatic breathing and lip bud breathing on the bed, as well as stretching and chest expansion exercises for a total of ten minutes. Then the patient went to the exercise room, and performed six minutes of aerobic exercise with an intensity equal to 60% of the walking test. In the control group, patients only perform physiotherapy exercises on the bed.

Participants/Inclusion and exclusion criteria

Inclusion criteria include age above 18 years, diagnosis of PH through echocardiography, PAP above 35, signing a written consent form to participate in the research project. Exclusion criteria include the patient's unwillingness to continue participating in the plan, active cancer, or any disorder preventing rehabilitation exercises.

Intervention groups

In the intervention group, patients perform physiotherapy exercises on the bed, including diaphragmatic breathing and lip bud breathing, as well as aerobic exercise. In the control group, patients only perform physiotherapy exercises on the bed.

Main outcome variables

The distance of 6 minutes walking test; glutathione peroxidase (GPx); Catalase (CAT); total antioxidant capacity (TAC); Forced Expiratory Volume in First Second (FEV1)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240413061474N2**
Registration date: **2024-06-22, 1403/04/02**
Registration timing: **prospective**

Last update: **2024-06-22, 1403/04/02**

Update count: **0**

Registration date

2024-06-22, 1403/04/02

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

2024-07-22, 1403/05/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aerobic exercises on antioxidant indices of pulmonary hypertension (PH) patients with chronic obstructive pulmonary disease (COPD)

Public title

The effect of aerobic exercises in pulmonary hypertension (PH) patients with chronic obstructive pulmonary disease (COPD)

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Age more than 18 years
Diagnosis of PH through echocardiography
Pulmonary arterial pressure (PAP) more than 35
Signing the written consent form to participate in the research project

Exclusion criteria:

The patient's unwillingness to continue participating in the research project, active cancer, or any disorder prohibiting rehabilitation exercises

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Blinding (investigator's opinion)

Single blinded

Blinding description

Clinical evaluations will be performed by blinded evaluators who are unaware of the interventions assigned to the participants. So that each evaluator receives codes for each patient that are related to training groups. Therefore, the type of grouping and the type of intervention cannot be identified by the clinical assessor.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tuberculosis and Lung Disease
Research Institute of Shahid Beheshti University o

Street address

Darabad, Masih Daneshvari Hospital

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2024-04-23, 1403/02/04

Ethics committee reference number

IR.SBMU.NRITLD.REC.1403.016

Health conditions studied**1****Description of health condition studied**

Pulmonary hypertension (PH) with chronic obstructive pulmonary disease (COPD)

ICD-10 code

I27.2

ICD-10 code description

Other secondary pulmonary hypertension

Primary outcomes**1****Description**

Test distance of 6 minutes walk

Timepoint

Before and after rehabilitation

Method of measurement

Six minute walk test

Secondary outcomes**1****Description**

Glutathione peroxidase (GPx)

Timepoint

Before and after rehabilitation

Method of measurement

Spectrophotometry

2

Description

Catalase

Timepoint

Before and after rehabilitation

Method of measurement

Spectrophotometry

3

Description

Total antioxidant capacity

Timepoint

Spectrophotometry

Method of measurement

Before and after rehabilitation

Intervention groups

1

Description

Intervention group: In the intervention group, COPD patients diagnosed with pulmonary hypertension according to the protocol, perform aerobic exercises including diaphragmatic breathing exercises and lip bud breathing on the bed, as well as stretching exercises and chest expansion for a total of ten minutes. Then the patient goes to the exercise room, and with an intensity equivalent to 60% of the six-minute walking test, they perform aerobic exercise as follows: At first, the patient walks on a treadmill for 5 minutes at a speed of 1 km/h. (warming up), then he exercises for 15 minutes at a speed equal to 60% of the walking test for six minutes (he continues to walk) and in the last 5 minutes he slows down again at a speed of 2 km/h. slow down. After the end of the exercise, stretching exercises for the lower limb muscles are performed on the treadmill for 10 minutes.

Category

Rehabilitation

2

Description

Control group: In the control group, COPD patients diagnosed with pulmonary hypertension only perform physical therapy exercises on the bed, including diaphragmatic breathing and lip bud breathing on the bed, as well as stretching exercises and chest expansion for a total of ten minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Kosar Mohammadnejad

Street address

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kosar.mohammadnejad@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

City

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1983969411

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Email

zarghi@sbmu.ac.ir

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

Seyed Bashir Mirtajani

Position

دکتری ژنتیک مولکولی

Latest degree

Ph.D.

Other areas of specialty/work

Molecular genetics

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bashirmirtajani67@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Aboozar Mojbian

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

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Full name of responsible person

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