Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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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
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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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
Seyed Bashir Mirtajani
Position

دکتری ژنتیک مولکولی

Latest degree
Ph.D.

Other areas of specialty/work
Molecular genetics

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Position
Assistant Professor

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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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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