Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of implementing an exercise program with blood flow restriction on clinical and functional factors of chronic obstructive pulmonary disease

Protocol summary

Study aim

The effect of implementing an exercise program with blood flow restriction on clinical and functional factors of chronic obstructive pulmonary disease patients at Masih Daneshvari Hospital

Design

A clinical trial with a control group, with parallel groups, without blinding, randomized, phase 3 on 20 patients. A table of random numbers was used for randomization.

Settings and conduct

The current study is a clinical trial on chronic obstructive pulmonary disease(COPD) patients referred to Masih Deneshvari Hospital in Tehran. Patients are randomly divided into two groups. A six-minute walk test, sit to stand and dynamometry were performed, then the patients of the intervention group were given breathing exercises, including diaphragmatic breathing and chest expansion, and then for 20 minutes with BFR with low load intermittently from a stationary bicycle. use. In the control group, patients only do breathing exercises.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients with stable chronic obstructive pulmonary disease, able to perform aerobic exercise, between the ages of 40 and 65 years, and exclusion criteria include • sickle cell anemia, history of venous thromboembolism, patients with cancer (mass), patients with hemoptysis, Patients with pulmonary abscess, patients with fibrosis, immunocompromised patients, patients with cardiovascular system instability.

Intervention groups

In the intervention group, training of breathing exercises including diaphragmatic breathing and chest expansion and then intermittently using a stationary bike for 20 minutes along with blood flow restriction (BFR) with low load. In the control group, patients only do breathing exercises.

Main outcome variables

Quadriceps strength; Shortness of breath; sports capacity; Blood oxygen saturation percentage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240203060888N1**
Registration date: **2024-05-28, 1403/03/08**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-28, 1403/03/08**
Update count: **0**

Registration date

2024-05-28, 1403/03/08

Registrant information

Name

Mohsen Abedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2712 1000

Email address

mohsenabedi110@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-20, 1403/02/01

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 implementing an exercise program with blood flow restriction on clinical and functional factors of chronic obstructive pulmonary disease

Public title

Exercise program with blood flow restriction in chronic obstructive pulmonary disease patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Sustained chronic obstructive disease Ability to do aerobic exercise Age 40 to 65 years

Exclusion criteria:

History of venous thromboembolism History of cancer Patients with hemoptysis Patients with pulmonary abscess Patients with fibrosis patients with immune system deficiency Patients with instability of the cardiovascular system

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is Random Permuted Blocks. For this purpose, two treatment groups A and B are defined as groups AB and BA. Then random table numbers are defined in the range of 0 to 9. We consider numbers 0 to 4 for block AB and numbers 5 to 9 for group BA. Then random numbers are selected from the table. The number 0 is related to block AB, and after that two people enter this block, the first person receives treatment A and the second person receives treatment B. In the same way, for other people, groups are treated. Although in this method, the number of observations of both groups will be the same, but due to the small size of the blocks, the possibility of predicting the treatment group by the person performing it is high. To solve this problem: the randomization list will be done bilaterally before the start of the study by a person outside the treatment staff. It also increased the block size. In the example, blocks with two treatments and 20 patients are designed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of the Rehabilitation Faculty of Shahid Beheshti University

Street address

Damavand Street (New Tehran), Imam Hossein (AS) Square

City

Tehran

Province

Tehran

Postal code

1616913111

Approval date

2024-02-04, 1402/11/15

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.692

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

Dyspnea

Timepoint

Before and after rehabilitation

Method of measurement

Borg scale

2

Description

Quadriceps strength

Timepoint

Before and after rehabilitation

Method of measurement

Dynamometer

3

Description
Sports capacity
Timepoint
Before and after rehabilitation
Method of measurement
Six-minute walk and sit to stand tests

Secondary outcomes

empty

Intervention groups

1

Description
At first, six-minute walking tests, assessment of the Borg standard questionnaire (to measure dyspnea and fatigue), 30-second sit-and-stand test, and evaluation of quadriceps muscle strength with the help of a dynamometer are performed. Pulse oximetry is also used to determine the percentage of oxygen saturation. Diaphragmatic breathing and chest expansion are taught to patients at the beginning of each cycle. Then the patients use a stationary bike for 20 minutes with BFR intermittently and with a low load. The duration of this exercise is 4 periods of 5 minutes.
Category
Rehabilitation

2

Description
Control group: Patients perform breathing exercises including diaphragmatic breathing and chest expansion.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Mohsen Abedi
Street address
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1956944413
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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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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
Mohsen Abedi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Researcher

Latest degree

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