Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the improvement in activity of patients with chronic obstructive pulmonary disease following pulmonary rehabilitation based on mMRC and 6mwt

Protocol summary

Study aim
Investigating the improvement in activity of patients with chronic obstructive pulmonary disease following pulmonary rehabilitation based on mMRC and 6mwt

Design
The present study is a before-and-after clinical trial without a control group on 31 patients.

Settings and conduct
In this pre-post clinical trial without a control group, 31 patients with Chronic Obstructive Pulmonary Disease referred to Rajaie Hospital in Karaj will undergo a comprehensive pulmonary rehabilitation program for 8 weeks. Patients will be assessed for the intended outcomes before and after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Confirmed diagnosis of Chronic Obstructive Pulmonary Disease based on spirometry؛ Clinically stable condition (no hospitalization or exacerbation in the last 4 weeks)؛ Ability to understand, cooperate, perform tests, and attend sessions regularly. Exclusion Criteria: Unstable or severe cardiovascular disease (e.g., unstable angina, severe heart failure)؛ Severe mobility limitations (orthopedic or neurological) preventing exercise؛ Concurrent participation in other rehabilitation programs or unwillingness to follow the protocol.

Intervention groups
The intervention group will receive a comprehensive pulmonary rehabilitation program under the supervision of a physiotherapist for a duration of 8 weeks, with a frequency of 2 or 3 sessions per week. Each session will last between 30 to 60 minutes, depending on the patient’s tolerance, and will include aerobic exercises, breathing exercises (diaphragmatic breathing, huffing), and the use of an incentive spirometer.

Main outcome variables
Six-Minute Walk Test, Dyspnea level, Disease’s impact on quality of life, FEV1/FVC ratio, FEV1, FVC

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191104045328N43**
Registration date: **2025-10-08, 1404/07/16**
Registration timing: **prospective**

Last update: **2025-10-08, 1404/07/16**
Update count: **0**

Registration date
2025-10-08, 1404/07/16

Registrant information

Name
Amin Haji seyyed hoseini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3366 7583

Email address
amin.medstu@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-17, 1404/07/25

Expected recruitment end date
2025-12-06, 1404/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the improvement in activity of patients with chronic obstructive pulmonary disease following pulmonary rehabilitation based on mMRC and 6mwt

Public title
The Effect of Pulmonary Rehabilitation on Improving the Quality of Life in Patients with Chronic Obstructive Pulmonary Disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed diagnosis of Chronic Obstructive Pulmonary Disease based on spirometry. Clinically stable condition (no hospitalization or exacerbation in the last 4 weeks). Ability to understand, cooperate, perform tests, and attend sessions regularly.
Exclusion criteria:
Unstable or severe cardiovascular disease (e.g., unstable angina, severe heart failure). Severe mobility limitations (orthopedic or neurological) preventing exercise. Concurrent participation in other rehabilitation programs or unwillingness to follow the protocol.

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **31**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Alborz University of Medical Sciences
Street address
Research and Technology Deputy, Alborz University of Medical Sciences, Saffarian Alley, 45 Metri Golshahr Ave., Karaj, Alborz, Iran.
City
Arak
Province
Markazi
Postal code
3198764653

Approval date
2025-07-13, 1404/04/22

Ethics committee reference number
IR.ABZUMS.REC.1404.107

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
Six-minute walk test

Timepoint
Before and after the intervention

Method of measurement
Distance covered in the six-minute walk test

2

Description
Level of Dyspnea

Timepoint
Before and after the intervention

Method of measurement
Modified Medical Research Council Questionnaire

3

Description
Disease’s impact on quality of life

Timepoint
Before and after the intervention

Method of measurement
Chronic Obstructive Pulmonary Disease Assessment Test

4

Description
Forced Expiratory Volume in 1 second (FEV1).

Timepoint
Before and after the intervention

Method of measurement
Spirometry

5

Description
Forced Vital Capacity (FVC)
Timepoint
Before and after the intervention
Method of measurement
Spirometry

6

Description
FEV1/FVC index
Timepoint
Before and after the intervention
Method of measurement
Spirometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will undergo a comprehensive pulmonary rehabilitation program supervised by a physiotherapist for a duration of eight weeks, with a frequency of two to three sessions per week. Each session will last between 30 and 60 minutes, depending on the patient's tolerance, and will include aerobic exercises, respiratory training (diaphragmatic breathing and huffing), as well as the use of an incentive spirometer.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaee Hospital, Karaj
Full name of responsible person
Dr. Mohammad Kargari Kashkouyeh
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Safarian Alley, 45-Metri Golshahr, Deputy of Research, Alborz University of Medical Sciences, Karaj, Iran
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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
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Dr. Behnaz Movahedi
Position
Associate professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.
When the data will become available and for how long
Access will be from 2026/2/21 to 2029/2/21 for 3 years.
To whom data/document is available
University researchers
Under which criteria data/document could be used
Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.
From where data/document is obtainable
Academic researchers and university faculty members, after establishing contact with the relevant professor via message or email, may request access to and utilization of data from Dr. Ghazal Erfanifar. Dr. Ghazal Erfanifar: Phone: 09183615107 Email: erfanifarghazaal@gmail.com, Address: Shahid Rajaee Educational and Medical Center, Shahid Rajaee Street, Hesarak District, Karaj, Alborz Province, Iran
What processes are involved for a request to access data/document
Letter writing should be done with professors and universities.
Comments