

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 seyed 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 Rajaei Hospital, Karaj

Full name of responsible person

Dr. Mohammad Kargari Kashkouyeh

Street address

Shahid Rajaei Educational and Medical Center,
Shahid Rajaei Street, Hesarak, Karaj, Iran

City

Karaj

Province

Alborz

Postal code

3197635141

Phone

+98 26 3455 2001

Email

kargarkoshkooeh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr. Alireza Dehghan Niri

Street address

Safarian Alley, 45-Metri Golshahr, Deputy of
Research, Alborz University of Medical Sciences,
Karaj, Iran

City

Karaj

Province

Alborz

Postal code

3198764653

Phone

+98 26 3464 3774

Email

Research@abzums.ac.ir

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

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Shahid Rajaei Educational and Medical Center,
Shahid Rajaei Street, Hesarak, Karaj, Iran

City

Karaj

Province

Alborz

Postal code
3197635141
Phone
+98 26 3455 2001
Email
behmov@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Dr. Mohammad Kargari Kashkouyeh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Shahid Rajaei Educational and Medical Center,
Shahid Rajaei Street, Hesarak, Karaj, Iran
City
Karaj
Province
Alborz
Postal code
3197635141
Phone
+98 26 3455 2001
Email
kargarkoshkooeh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Dr. Ghazal Erfanifar
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Shahid Rajaei Educational and Medical Center,
Shahid Rajaei Street, Hesarak, Karaj, Iran
City
Karaj
Province
Alborz
Postal code
3197635141

Phone
+98 26 3455 2001
Email
erfanifarghazaal@gmail.com

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 Rajaei Educational and Medical Center, Shahid Rajaei 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