Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of using the inspiratory muscle training device (IMT) on the thickness and excursion of the diaphragm of COPD patients undergoing lung rehabilitation

Protocol summary

Study aim
Investigating the effect of using the inspiratory muscle training device (IMT) on the thickness and excursion of the diaphragm of COPD patients undergoing lung rehabilitation

Design
A controlled, single-blind, randomized, phase 3 clinical trial with parallel groups on 22 patients, using a random number table for randomization.

Settings and conduct
Two groups of patients hospitalized in the Pulmonary Rehabilitation Department of Masih Hospital perform rehabilitation exercises, with the difference that in the intervention group, patients also use the IMT device. The radiologist who performs and evaluates the patients' ultrasound is blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria included age over 18 years, diagnosis of COPD based on GOLD, literacy, and exclusion criteria included hemoptysis, embolism, lung cancer, pneumothorax, acute cardiovascular problems, diaphragmatic paralysis, severe shortness of breath preventing testing, patient unwillingness to continue participating in the research project, and not having a smartphone.

Intervention groups
In the intervention group, patients perform daily pulmonary rehabilitation exercises along with aerobic exercise during 2 weeks of hospitalization. Patients use the IMT device. Patients continue the rehabilitation process at home as remote rehabilitation with the IMT device (for 6 weeks). In the control group, patients perform daily breathing exercises and stretching exercises along with aerobic exercise during 2 weeks of hospitalization. Then they continue their rehabilitation program at home for 6 weeks.

Main outcome variables
Exercise capacity, dyspnea, health-related quality of life, sit to stand test, S-index derived from IMT, diaphragm excursion and thickness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200611047727N7**
Registration date: **2025-06-23, 1404/04/02**
Registration timing: **prospective**

Last update: **2025-06-23, 1404/04/02**
Update count: **0**

Registration date
2025-06-23, 1404/04/02

Registrant information

Name
Maryam Sadat Mirenayat

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2610 5050

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mirenayat@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-23, 1404/05/01

Expected recruitment end date
2026-01-21, 1404/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of using the inspiratory muscle training device (IMT) on the thickness and excursion of the diaphragm of COPD patients undergoing lung rehabilitation

Public title
The effect of using the inspiratory muscle training device (IMT) on the thickness and excursion of the diaphragm of COPD patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Diagnosis of COPD based on GOLD
Exclusion criteria:
Hemoptysis embolism lung cancer pneumothorax acute cardiovascular problems diaphragmatic paralysis severe dyspnea preventing testing patient's unwillingness to continue participating in the research project
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **221**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Simple, Randomization unit: Individual, Randomization tool: Random number table. Simple randomization method is used for randomization with the help of a random number table. For this purpose, two groups are named A and B. We choose one of the rows of the random number table at will and the numbers of each row will be between 0 and 9. We assign the numbers 0-4 to treatment A and the numbers 5-9 to treatment B.
Blinding (investigator's opinion)
Single blinded
Blinding description
Ultrasound scans of patients are performed by an experienced radiologist blind to the patient's other tests (on two occasions before the start of rehabilitation and at the end of the rehabilitation period).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway
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Tehran
Province
Tehran
Postal code
1956944413
Approval date
2025-05-27, 1404/03/06
Ethics committee reference number
IR.SBMU.MSP.REC.1404.114

Health conditions studied

1

Description of health condition studied
Chronic obstructive pulmonary disease
ICD-10 code
J44
ICD-10 code description
Other chronic obstructive pulmonary disease

Primary outcomes

1

Description
Diaphragmatic excursion
Timepoint
At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation
Method of measurement
Ultrasound

2

Description
Diaphragmatic thickness
Timepoint
At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation
Method of measurement
Ultrasound

3

Description

Forced vital capacity (FVC)

Timepoint

At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation

Method of measurement

Spirometry

4

Description

Forced expiratory volume in one second (FEV1)

Timepoint

At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation

Method of measurement

Spirometry

5

Description

Predicted FVC

Timepoint

At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation

Method of measurement

Spirometry

Secondary outcomes

1

Description

Six minute walk test distance

Timepoint

At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation

Method of measurement

Six minute walk test

2

Description

Dyspnea

Timepoint

At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation

Method of measurement

Based on modified medical research council dyspnea scale questionnaire

3

Description

Quality of life

Timepoint

At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation

Method of measurement

Based on the St. George questionnaire

Intervention groups

1

Description

Intervention group: Patients are hospitalized for 2 weeks and during this time they perform daily pulmonary rehabilitation exercises including diaphragmatic breathing, pursed lip breathing and respiratory stretching exercises along with aerobic exercise. In addition, patients use the IMT device. After 2 weeks, patients are discharged after receiving a home pulmonary rehabilitation program and exercise training. Patients continue their rehabilitation process at home as remote rehabilitation with the IMT device (for 6 weeks). To use the IMT device, the patient performs 30 repetitions in the morning and 30 repetitions in the afternoon every day, and the resistance of the device is gradually increased. At the end of 6 weeks, the patient returns to the hospital (rehabilitation department) and the desired evaluations will be performed.

Category

Treatment - Other

2

Description

Control group: Patients are hospitalized for 2 weeks and during this period, they perform daily breathing exercises including diaphragmatic breathing, pursed lip breathing, and respiratory stretching exercises for 20 minutes on the bed and under the direct supervision of a physiotherapist, along with aerobic exercise including at least 15 minutes of walking on a treadmill at a maximum speed equivalent to 80% of the six-minute walk test. After two weeks, patients are discharged after receiving a remote rehabilitation program and continue their rehabilitation program at home (under the supervision of the hospital rehabilitation team) for 6 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Maryam Sadat Mirenayat

Street address

Masih Daneshvari Hospital, Daarabad

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Afshin Zarghi
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Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway
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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
Masoumeh Zoghali
Position
Assistant professor
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Person responsible for updating data

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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