

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of rehabilitation with and without Non Invasive Ventilation on change in pulmonary function and CAT scores of COPD patients at Masih Daneshvari Hospital

Protocol summary

Summary

Objective: Effect of rehabilitation with and without non-invasive ventilation on lung function and COPD assessment test particularly for patients admitted to Masih daneshvari hospital in autumn and winter 1395. Study design: Randomized, double-blind, placebo-controlled, single-center, phase two and three trials. Study population: all patients with chronic obstructive pulmonary disease referring to Masih daneshvari hospital in the fall and winter of 1395 Inclusion criteria: (1) identifying chronic obstructive pulmonary disease, (2) the satisfaction of participating in the study, (3) the Consciousness to complete the tests Exclusion criteria: (1) inability to carry out the rehabilitation, (2) the occurrence of exacerbation or disease attack Sample Size: 50 Interventions include breathing exercises and physical therapy, pulmonary rehabilitation program (3 times a week 3 weeks) and concurrent use of non-invasive ventilation Implications of the study: the distance walked in 6-minute walk test, measurement values: venous blood gas analysis, pulmonary function tests, Chronic Obstructive Pulmonary Diseases assessment questionnaire

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102927929N3**
Registration date: **2017-02-14, 1395/11/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-14, 1395/11/26

Registrant information

Name

Atefeh Fakharian

Name of organization / entity

National research institute of tuberculosis and lung diseases

Country

Iran (Islamic Republic of)

Phone

+98 21 2712 2541

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-03-18, 1395/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of rehabilitation with and without Non Invasive Ventilation on change in pulmonary function and CAT scores of COPD patients at Masih Daneshvari Hospital

Public title

Effect of rehabilitation with and without Non Invasive Ventilation among COPD subjects

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: identifying chronic obstructive pulmonary disease; the satisfaction of participating in the study; The Consciousness of subjects
Exclusion criteria: inability to carry out rehabilitation; the occurrence of exacerbation or disease attack

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-Chancellor in Research Affairs of Shahid Beheshti
University of Medical Sciences

Street address

7th Floor, Bldg No.2 , Arabi Ave, Daneshjoo Blvd,
Velenjak,

City

Tehran

Postal code

Approval date

2016-04-14, 1395/01/26

Ethics committee reference number

IR.SBMU.MSP.REC.1395.235

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

Distance covered during 6 minutes

Timepoint

Before and immediately after intervention

Method of measurement

six minute walk test

2

Description

COPD assessment test score

Timepoint

Before and immediately after intervention

Method of measurement

COPD assessment test questionnaire

Secondary outcomes

1

Description

Forced expiratory volume in 1st second

Timepoint

Before and immediately after intervention

Method of measurement

spirometry

2

Description

pressure of CO2

Timepoint

Before and immediately after intervention

Method of measurement

Venus blood gas

Intervention groups

1

Description

Control group: 3 session/week for 3 weeks of rehabilitation including respiratory exercise and exercise therapy and Non invasive ventilation mask while the device is off.

Category

Treatment - Devices

2

Description

Intervention group: 3 sessions/ week for 3 weeks of rehabilitation including respiratory exercise and exercise therapy and Non Invasive Ventilation while the device is on.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih daneshvari hospital

Full name of responsible person

Marzie Mobininezhad

Street address

Darabad Avenue, Shahid Bahonar roundabout

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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7th Floor, Bldg No.2 , Arabi Ave, Daneshjoo Blvd, Velenjak

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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

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Atefeh Fakharian

Position

pulmonologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Atefeh Fakharian

Position

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Other areas of specialty/work

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Person responsible for updating data

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Marzie Mobininezhad

Position

Resident of Internal medicine

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty