

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The comparison of effect of incentive abdominal breathing device with normal abdominal breathing on the respiratory condition of chronic obstructive pulmonary disease

Protocol summary

Summary

This study is a randomized clinical trial. It aims to compare the effect of the incentive abdominal breathing device with normal abdominal breathing on the respiratory condition of chronic obstructive pulmonary disease. The population of the study is COPD patients admitted to the specialized clinic of Imam Reza Hospital in Mashhad. Inclusion criteria: content with the inclusion in study; ages from 18 to 65 years; chronic obstructive pulmonary disease confirmed by a physician; no signs of lung infection. Exclusion criteria: respiratory infection and fever while being studied. The sample size is 35 patients in each group were considered as the participants of the current study. In the experimental group, the incentive abdominal breathing device is fastened to the patient's abdomen, then they are asked to do abdominal breathing for 100 times (in 10 steps). This means that with the expansion of the abdominal muscles, the air inside the plastic tube goes into the balloon and between each 10 abdominal breathing, breathe normally for one minute. The patients in the control group are asked to put one hand on their stomach and one hand on their chest, then they do 100 abdominal breathing in 10 steps so that the stomach has the most and the chest has the least movement. The patients are asked to breathe normally between each 10 abdominal breath. Interventions take place twice a day in the morning and evening for 14 days. Clinical status COPD form, spirometry indices form, determine the severity of dyspnea form and breathing pattern indices for two groups will be completed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102224646N1**

Registration date: **2016-08-10, 1395/05/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-10, 1395/05/20

Registrant information

Name

Mehdi Golmohammadi Kavak

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 4612 5301

Email address

golmohammadikm2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of effect of incentive abdominal breathing device with normal abdominal breathing on

the respiratory condition of chronic obstructive pulmonary disease

Public title

The comparison of effect of incentive abdominal breathing device with normal abdominal breathing on the respiratory condition of chronic obstructive

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: For inclusion is satisfied; Chronic obstructive pulmonary disease has been approved by a pulmonary specialist and clinical results; FEV1 less than 80 percent of the index predicted and FEV1 / FVC ratio less than 70 percent; no Signs of lung infection, according psychiatrists lung; Aged 18 to 65 years; Not having a size too large or too small; No history of chest and abdominal surgery; No history of neuromuscular disorders; Lack of heart disease. Exclusion criteria: Respiratory infection and fever while studying; Deterioration of the patient or require hospitalization for any reason; The risk of heart problems and cardiac involvement during the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Mashhad University of Medical Sciences

Street address

Qureshi building, university St., Mashhad, Khorasan Razavi

City

Mashhad

Postal code

91388-13944

Approval date

2015-12-05, 1394/09/14

Ethics committee reference number

IR.MUMS.REC.1394.570

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease

ICD-10 code

J47

ICD-10 code description

Chronic lower respiratory diseases

2

Description of health condition studied

Chronic Obstructive Pulmonary Disease

ICD-10 code

J40

ICD-10 code description

Chronic lower respiratory diseases

Primary outcomes

1

Description

FEV1

Timepoint

Before the intervention, day 7, the end of the study (day 14)

Method of measurement

registration forms spirometric indices

2

Description

FVC

Timepoint

Before the intervention, day 7, the end of the study (day 14)

Method of measurement

registration forms spirometric indices

3

Description

FEV1/FVC

Timepoint

Before the intervention, day 7, the end of the study (day 14)

Method of measurement

registration forms spirometric indices

4

Description

PEFR

Timepoint

Before the intervention, day 7, the end of the study (day 14)

Method of measurement

registration forms spirometric indices

5

Description

MIP

Timepoint

Before the intervention, day 7, the end of the study (day 14)

Method of measurement

registration forms spirometric indices

6

Description

MVV

Timepoint

Before the intervention, day 7, the end of the study (day 14)

Method of measurement

registration forms spirometric indices

7

Description

Tidal volume

Timepoint

Before the intervention, day 7, the end of the study (day 14)

Method of measurement

registration forms spirometric indices

8

Description

Dyspnea

Timepoint

Before the intervention, day 7, the end of the study (day 14)

Method of measurement

numerical rating scale of Dyspnea

9

Description

Respiratory rate

Timepoint

Before the intervention, day 7, the end of the study (day 14)

Method of measurement

registration forms spirometric indices

10

Description

Disease severity

Timepoint

Before the intervention, day 7, the end of the study (day 14)

Method of measurement

copd assesment test(cat)

Secondary outcomes

empty

Intervention groups

1

Description

In the experimental group, the incentive abdominal breathing device to the patient's abdomen is closed. Then to 100 times (in 10 steps) to do abdominal breathing. This means that with the expansion of the abdominal muscles, the air inside the plastic tube into the balloon And in between each 10 abdominal breathing, take a minute to do normal breathing. Interventions do 14 days and twice a day in the morning and evening.

Category

Rehabilitation

2

Description

In the control group, patients one hand on his/her stomach and put other hand on chest And 100 times (in 10 steps) do abdominal breathing so that the chest have the largest and abdomen have least displacement. Among the 10 abdominal breathing, take a minute to do normal breathing. Interventions do 14 days and twice a day in the morning and evening.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Clinic of Imam Reza, Mashhad

Full name of responsible person

Mehdi Golmohammadi Kavak

Street address

Hospital Imam Reza, Mashhad, Khorasan Razavi

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nursing School, Mashhad University of Medical Sciences

Full name of responsible person

Ms. Zahra Sadat manzari

Street address

School of Nursing, Doktora crossroads, Mashhad,
Khorasan Razav

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Nursing School, Mashhad 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

Mashhad School of Nursing

Full name of responsible person

Mehdi Golmohammadi Kavaki

Position

Nursing Graduate Student

Other areas of specialty/work

Street address

School of Nursing, Doktora crossroads, Mashhad,
Khorasan Razav

City

Mashhad

Postal code

9138813944

Phone

+98 51 4612 5301

Fax

+98 51 3859 7313

Email

golmohammadikm921@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad School of Nursing

Full name of responsible person

Haji Mohmmad Norouzi

Position

Master of nursing

Other areas of specialty/work

Street address

School of Nursing, Crossroads Doktora, Mashhad,
Khorasan Razav

City

Mashhad

Postal code

9138813944

Phone

+98 51 3859 1511

Fax

+98 51 3859 7313

Email

Norozihm@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mehdi Golmohammadi Kavaki

Position

Nursing Graduate Student

Other areas of specialty/work

Street address

School of Nursing, Doktora crossroads, Mashhad,
Khorasan Razavi, Iran

City

Mashhad

Postal code

9138813944

Phone

+98 51 4612 5301

Fax

+98 51 3859 7313

Email

golmohammadikm921@mums.ac.ir

Web page address

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