Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, spirometery 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