

# 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*