

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The comparison of inspiratory resistive muscle training with incentive spirometer on improving respiratory function and dyspnea in COPD patients

Protocol summary

Summary

This study compared the use of inspiratory resistive muscle training (IMT) by powerbreathe to incentive spirometry on selected measures of pulmonary function and dyspnea. A total of 30 stable patients with moderate COPD (FEV1/ FVC<70%, FEV1<80% predicted) according to the criteria of the American Thoracic Society were randomly assigned to either an IMT or IS treatment group. All subjects were trained daily in two sessions of 15 minute each, 4 days a week, for 4 weeks. In the IMT group, the training was performed using a threshold inspiratory muscle trainer (POWERbreathe; Gaiam Ltd; Southam, Warwickshire, UK). In the IS group the training was performed using a volumetric exercisers (Respiflo; Tyco Health Care Ltd; UK). Functional lung parameters, respiratory pattern and dyspnea were compared in the both training groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105096422N1**

Registration date: **2011-10-02, 1390/07/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-10-02, 1390/07/10

Registrant information

Name

Marjan Farzad

Name of organization / entity

Mashhad University of Nursing and Midwifery

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Recruitment status

Recruitment complete

Funding source

Mashhad University Of Medical Sciences

Expected recruitment start date

2011-04-30, 1390/02/10

Expected recruitment end date

2011-08-01, 1390/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of inspiratory resistive muscle training with incentive spirometer on improving respiratory function and dyspnea in COPD patients

Public title

Respiratory rehabilitation in lung disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Obtaining informed consent, The chronic obstructive pulmonary disease diagnosed and confirmed by lung specialist and through paraclinical tests; fev1<80% predicted and fev1/fvc<70% (stagell, stable patients); clear Lungs, age 40-65; basic spirometry other than "Asthma"; No smoking at least for 3 months Exclusion criteria: Refuse to participate in research; not taking part in training for 4 weeks prior to

the study; fever or respiratory infection; Respiratory or cardiac failure

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University Of Medical Sciences

Street address

Vice-chancellor for Reseach, Mashhad University of Medical Sciences, Daneshgah Street, Mashhad

City

Mashhad

Postal code

91735951

Approval date

2011-04-30, 1390/02/10

Ethics committee reference number

89762

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease (Chronic Bronchitis,Amphysema)

ICD-10 code

J41, J43

ICD-10 code description

simple and mucopurulent chronic bronchitis,Emphysema

Primary outcomes

1

Description

Maximal Voluntary Ventilation

Timepoint

before intervention, end of week 2, end of week 4

Method of measurement

L/m, by Hi 801 spirometer

2

Description

Plmax

Timepoint

before intervention, end of week 2, end of week 4

Method of measurement

Cm/H20, mouth pressure meter

3

Description

Forced Vital Capasity

Timepoint

before intervention, end of week 2,end of week 4

Method of measurement

L, by Hi 801 spirometer

4

Description

Peek Expiratory Flow Rate

Timepoint

before intervention, end of week 2, end of week 4

Method of measurement

L/s, by Hi 801 spirometer

5

Description

Forced Expiratory Volume in One Second

Timepoint

before intervention, end of week 2, end of week 4

Method of measurement

L, by Hi 801 spirometer

6

Description

Tidal Volume

Timepoint

before intervention, end of week 2, end of week 4

Method of measurement

L, by Hi 801 spirometer

7

Description

Respiratory Rate

Timepoint

before intervention, end of week 2, end of week 4

Method of measurement

Count chest rising and coming down for one full minute, by watch OMax

Secondary outcomes

1

Description

dyspnea

Timepoint

before intervention, end of week 2, end of week 4

Method of measurement

Numerical Rating Scale (0-10)

2

Description

Respiratory pattern

Timepoint

before intervention, end of week 2. end of week 4

Method of measurement

with measuring depth of respiration (according to tidal volume, L) and respiratory rate by watch, Breath/minute

Intervention groups

1

Description

Intervention 1: the training was performed using a volumetric exercisers (Respiflo; Tyco Health Care Ltd; UK)/ 10 to 15 times in two sessions of 15 minutes each morning and in the afternoon /4 days a week for 4 weeks.

Category

Rehabilitation

2

Description

Intervention2: the training was performed using a threshold inspiratory muscle trainer (POWERbreathe; Gaiam Ltd; Southam, Warwickshire, UK)/ daily in two sessions of 15 minute each morning and in the afternoon/4 days a week, for 4 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Emamreza Hospital, Mashhad

Full name of responsible person

Dr. Hossein Ahmadihoseiny, Lung Specialist, assistant professor of mashhad University of medical sci

Street address

Emamreza sq, Ebnesina street, Mashhad

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Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences, Research Section

Full name of responsible person

Dr. Mohammad Ramezani

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Ghoraishi Building, Research section, Daneshghah Street, Mashhad

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Grant name

شماره 663/511

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences, Research Section

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 University of Nursing and midwifery

Full name of responsible person

Abbas Heidary, Ph.D, Assistant professor of Mashhad University of Nursing and Midwifery

Position

PH.D in nursing

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