Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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% (stageII, 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
PImax

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
befor intervention, end of week 2, end of week4
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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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
663/511شماره
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
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Assistant Professor of Internal Group of Mashhad University of Medical Science, Lung Specialist

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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