

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

: Effects of inspiratory muscle training on fatigue and dyspnea in patients with chronic heart failure

Protocol summary

Summary

Objective: To determine the effect of inspiratory muscle training on the severity of dyspnea and fatigue in patients with chronic heart failure will Methods: This study is a clinical trial. Inclusion criteria included LVEF less than 40% on echocardiography, based on standard New York Heart Association Class 2 and 3 patients out of acute myocardial infarction and acute illness is .myarhay is infectious. A total of 100 patients randomly into two groups of intervention and control are blocked. Inspiratory muscle training for 6 weeks for patients in the intervention group performed. Before and after the intervention, the shortness of breath and fatigue using the Fatigue Severity Scale Fatigue Severity Scale (FSS) and Scale adjusted shortness of breath, Medical Research Council Modified Medical Research Council dyspnea scale (MRC) will be assessed. The control group received usual care, and at the beginning and end of six weeks, completed questionnaires and fatigue and shortness of breath is measured

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071324080N2**

Registration date: **2016-11-27, 1395/09/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-27, 1395/09/07

Registrant information

Name

Mohammad Gholami

Name of organization / entity

Lorestan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Lorestan University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

: Effects of inspiratory muscle training on fatigue and dyspnea in patients with chronic heart failure

Public title

: Effects of inspiratory muscle training on fatigue and dyspnea in patients with chronic heart failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 18-65 years; being clinically stable; left ventricular ejection fraction (LVEF) below 40%; New York Heart Association (NYHA) Class II and III; no change in medications over three months; Patients with cardiac pacemaker were included after 6 weeks after implementation. Exclusion criteria: having acute myocardial infarction; cognitive disorders; complex arrhythmias; uncontrolled hypertension; angina pectoris;

recent viral infections (6 months prior to study); orthopedic problems; and rheumatologic diseases.

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: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Lorestan University of Medical Sciences

Street address

Campus of Kamalvand Pardis, Lorestan University of Medical Sciences

City

Khorramabad

Postal code

6814993165

Approval date

2016-07-11, 1395/04/21

Ethics committee reference number

Lums.REC.1395.106

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

I50.9

ICD-10 code description

Heart failure, unspecified

Primary outcomes

1

Description

fatigue

Timepoint

immediately before intervention and 6 weeks after intervention

Method of measurement

fatigue severity scale (FSS)

Secondary outcomes

1

Description

Dyspnea

Timepoint

immediately before intervention and 6 weeks after intervention

Method of measurement

Modified Medical Research Council dyspnea scale(MRC)

Intervention groups

1

Description

Treatment group: Treatment group will perform Inspiratory Muscle Training (IMT) for 30min, 7 days per week, for 6weeks using the Threshold device (Respironics).each seven session will perform at home. Treatment group will receive IMT at 40% of Maximal inspiratory pressure (MIP), and training loads will adjust to maintain 40% of the MIP, weekly.

Category

Rehabilitation

2

Description

control group: control group will receive usual care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital

Full name of responsible person

Amir Hossein Hossein Pour

Street address

Campus of Kamalvand Pardis

City

Khorramabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lorestan University of Medical Sciences

Full name of responsible person

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Campus of Kamalvand Pardis, Lorestan University of Medical Sciences

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khorrarnabad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Lorestan 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

Lorestan University of Medical Sciences

Full name of responsible person

Amir Hossein Hossein Pour

Position

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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