

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of cardiac rehabilitation in patients with congestive heart failure

Protocol summary

Summary

This study is a randomized controlled trial that will evaluate the effects of cardiac rehabilitation in patients with congestive heart failure. Fifty ambulatory patients with CHF diagnosed and followed by the Cardiologist will be recruited to the study. Inclusion criteria: patient with NYHA classification 2 or 3 with ejection fraction less than 45 and older than 50 years old who is referred by cardiologist for cardiac rehabilitation. Exclusion criteria: diabetes mellitus; obstructive cardiomyopathy; arrhythmia; uncontrolled HTN(systolic blood pressure more than 200 and diastolic blood pressure more than 120); aortic stenosis; recent myocardial infarction; symptomatic pectoralis angina; patient with muscular or skeletal deformity that is limited physical activity and cardiac surgery. Patients will be randomized by using the sequence of random numbers either to case and control groups. All patients continue their recommended medication and diet during the study. The control groups continue their medication and are encouraged to perform their routine daily activities, whereas the exercise group participates in cardiac rehabilitation program in addition to their usual medication. The control group performs cardiac rehabilitation three times a week for 40 sessions. Each session begin with 10 minutes warm up and stretching exercise and proceeded with interval training method: 20 seconds with 50% maximal resistance and 40 seconds with 20% of maximal resistance (maximal resistance is measured with ramp test). This method continues up to 20 minutes and end with 10 minutes cool down and stretching exercise. Total duration of exercise is 30 minutes arm ergometry and 30 minutes leg ergometry. In this randomized controlled trial, ejection fraction and quality of life of all patients will be assessed at the beginning and at the end of the study (4 months later).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040517126N1**

Registration date: **2014-06-12, 1393/03/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-12, 1393/03/22

Registrant information

Name

Narges Mohassel

Name of organization / entity

Shiraz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 71 1229 6620

Email address

mohasel_n@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science

Expected recruitment start date

2014-04-09, 1393/01/20

Expected recruitment end date

2014-04-30, 1393/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of cardiac rehabilitation in patients with congestive heart failure

Public title

Effects of cardiac rehabilitation in patients with heart failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient with NYHA classification 2 or 3 with ejection fraction less than 45 and older than 50 years old who is referred by cardiologist for cardiac rehabilitation. Exclusion criteria: diabetes mellitus; obstructive cardiomyopathy; arrhythmia; uncontrolled HTN(systolic blood pressure more than 200 and diastolic blood pressure more than 120); aortic stenosis; recent myocardial infarction; symptomatic pectoralis angina; patient with muscular or skeletal deformity that is limited physical activity and cardiac surgery.

Age

From 50 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

shiraz university of medical science

Street address

zand street.shiraz university of medical science

City

shiraz

Postal code

Approval date

2014-03-09, 1392/12/18

Ethics committee reference number

CT-P092-4584

Health conditions studied

1

Description of health condition studied

Conjestic heart failure

ICD-10 code

I50.0

ICD-10 code description

Congestive heart failure

Primary outcomes

1

Description

Ejection fraction

Timepoint

Before intervention, one month after intervention

Method of measurement

Echocardiography

2

Description

Quality of life

Timepoint

Before intervention, one month after intervention

Method of measurement

SF 36 quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

the patients perform cardiac rehabilitation three times a week for 40 sessions.each session begin with 10 minutes warm up and stretching exercise and procede with interval training method :20 seconds with 50% maximal resistance and 40 seconds with 20% of maximal resistance(maximal resistance is measured with ramp test).this method continue up to 20 minutes and end with 10 minutes cool down and stretching exercise.total duration of exercise is 30 minutes arm ergometry and 30 minutes leg ergometry.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi hospital

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Physical Medicine and Rehabilitation ward, Shiraz
University of Medical Sciences

Full name of responsible person

Kaynush Homayouni

Street address

Shiraz University of Medical Sciences , Zand Street

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Physical Medicine and Rehabilitation ward, Shiraz
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**

Shiraz University of Medical Sciences

Full name of responsible person

Narges Mohassel

Position

Physical medicine and rehabilitation resident

Other areas of specialty/work**Street address**

Faghihi hospital

City

Shiraz

Postal code**Phone**

+98 71 1229 6620

Fax**Email**

mohasel_n@gmail.com; nargesmohassel@gmail.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Kaynush Homayouni

Position

Assistant professor

Other areas of specialty/work**Street address**

Faghihi hospital

City

Shiraz

Postal code**Phone**

+98 71 1231 9040

Fax**Email**

kayhomayouni@yahoo.com

nargesmohassel@gmail.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Narges Mohassel

Position

Physical medicine and rehabilitation resident

Other areas of specialty/work**Street address**

Faghihi hospital

City

Shiraz

Postal code**Phone**

+98 71 1229 6620

Fax**Email**

mohasel_n@sums.ac.ir; nargesmohassel@gmail.com

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