Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of cardiac rehabilitation in patients with conjestive 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 conjestive 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
Conjestive 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 quastionnaire

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 streching 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 streching 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 Sciencs
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 Sciencs
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
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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