

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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

Congestive 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**

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**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

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## 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*