

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The assessment of cardiac rehabilitation's effect on echocardiographic parameters of Left Ventricular systolic function in patients treated by Primary Percutaneous Coronary Intervention due to acute ST-segment Elevation Myocardial Infarction

Protocol summary

Summary

The aim of this study is to determine the effects of cardiac rehabilitation on echocardiographic parameters of Left Ventricular (LV) systolic function in patients treated by Primary Percutaneous Coronary Intervention (PPCI) due to acute ST-segment Elevation Myocardial Infarction (STEMI). The sample size was statistically considered to be at least fifty patients. Therefore, fifty nine patients who had inclusion criteria, were included randomly in two groups: rehabilitation (29 people) and control (30 people) after obtaining the informed written consent. Inclusion criteria: complete revascularization after PPCI and LV systolic dysfunction indicated by LV Ejection Fraction of 35-49%. Exclusion criteria: atrial fibrillation; more than mild LV hypertrophy in two-dimensional echocardiography; poor echocardiographic window; post-myocardial infarction angina; resting systolic blood pressure > 180 mmHg; resting diastolic blood pressure > 110 mmHg; symptomatic orthostatic change in systolic blood pressure > 20 mmHg; severe aortic stenosis; uncontrolled tachycardia or bradycardia; decompensated heart failure; uncontrolled diabetes mellitus; acute systemic illness; physical disability. The participants in two groups are matched for age and gender. The rehabilitation group participate in a comprehensive cardiac rehabilitation program including a supervised exercise training course, whereas the control individuals are just instructed of risk factor management. The cardiac rehabilitation program consists of 24 sessions and conducts over an 8-week period (three times per week). Each session lasts about one hour beginning with a warm-up (10 minutes) and follows by 40 minutes of aerobic exercise training using recumbent upper and lower extremity ergometers. The last 10 minutes is allocated to cool-down and all sessions finish by relaxation. The heart rate reserve is calculated

on the basis of individualized resting and maximal heart rate obtained by a exercise test before the start of cardiac rehabilitation program and the target heart rate is set up between 40-60% of the reserve as exercise intensity to achieve a moderate level. For all patients who complete the whole rehabilitation program, the exercise test is repeated at the end of sessions with the same protocol as the basic one and Metabolic Equivalents (METs) are calculated before and after the cardiac rehabilitation program. During the first week after acute STEMI, a baseline two-dimensional transthoracic echocardiography including speckle tracking echocardiography is done using a vivid E9 (General Electric) system and all measurements including LV Ejection Fraction, Fractional Shortening, Stroke Volume and mean Global Longitudinal LV Strain, are performed by one expert echocardiologist according to the latest recommendations of American Society of Echocardiography. The echocardiography will be repeated after the completion of the cardiac rehabilitation program in the rehabilitation group and after the same period in the control group. All the follow-up examinations use the same system as basic ones and the same echocardiologist, blinded to the patient assignment group analyzes them. After the completion of course, the values of echocardiographic parameters of LV systolic function will be compared statistically within and between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016103130613N1**

Registration date: **2017-04-22, 1396/02/02**

Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2017-04-22, 1396/02/02

Registrant information
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Recruitment status
Recruitment complete
Funding source
Shiraz Cardiovascular Research Center

Expected recruitment start date
2015-02-02, 1393/11/13
Expected recruitment end date
2016-01-01, 1394/10/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The assessment of cardiac rehabilitation's effect on echocardiographic parameters of Left Ventricular systolic function in patients treated by Primary Percutaneous Coronary Intervention due to acute ST-segment Elevation Myocardial Infarction

Public title
The role of cardiac rehabilitation after myocardial infarction

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: complete revascularization after Primary Percutaneous Coronary Intervention and Left Ventricular (LV) systolic dysfunction indicated by LV Ejection Fraction of 35-49%. Exclusion criteria: atrial fibrillation; more than mild LV hypertrophy in two-dimensional echocardiography; poor echocardiographic window; post-myocardial infarction angina; resting systolic blood pressure > 180 mmHg; resting diastolic blood pressure > 110 mmHg; symptomatic orthostatic change in systolic blood pressure > 20 mmHg; severe aortic stenosis; uncontrolled tachycardia or bradycardia; decompensated heart failure; uncontrolled diabetes mellitus; acute systemic illness; physical disability.

Age
From **35 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Shiraz University of Medical Sciences

Street address

School of Medicine, Zand Avenue

City

Shiraz

Postal code

Approval date

2015-02-01, 1393/11/12

Ethics committee reference number

93-7766

Health conditions studied

1

Description of health condition studied

Acute myocardial infarction

ICD-10 code

I21.9

ICD-10 code description

Acute myocardial infarction, unspecified

2

Description of health condition studied

Cardiac rehabilitation

ICD-10 code

Z50.0

ICD-10 code description

Cardiac rehabilitation

Primary outcomes

1

Description

Changes of Left Ventricular systolic function

Timepoint

At the beginning of the study and after 3 months

Method of measurement

Echocardiography

Secondary outcomes

1

Description

Changes of Left Ventricular volumes

Timepoint

At the beginning and after 3 months

Method of measurement

Echocardiography

Intervention groups

1

Description

The intervention group receives 24 sessions of cardiac rehabilitation program. Each session lasts about one hour beginning with a warm-up (10 minutes) and follows by 40 minutes of aerobic exercise training using recumbent upper and lower extremity ergometers. The last 10 minutes was allocated to cool-down and all sessions finish by relaxation.

Category

Rehabilitation

2

Description

The control group do not participate in cardiac rehabilitation program and are just instructed of risk factor management.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Maryam Tahamtan

Street address

Motahari Square

City

Shiraz

2

Recruitment center

Name of recruitment center

Shahid Faghihi Hospital

Full name of responsible person

Maryam Tahamtan

Street address

Zand Avenue

City

Shiraz

3

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Maryam Tahamtan

Street address

Astane Blvd

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz Cardiovascular Research Center

Full name of responsible person

Mohammad Javad Zibaee Nezhad

Street address

Mohammad Rasoul-Allah Research Tower, Khalili Avenue, Mollasadra Street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz Cardiovascular Research Center

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 Cardiovascular Research Center

Full name of responsible person

Maryam Tahamtan

Position

Researcher

Other areas of specialty/work

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Shiraz Cardiovascular Research Center

Full name of responsible person

Maryam Tahamtan

Position

Researcher

Other areas of specialty/work

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Fax

Email

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz Cardiovascular Research Center

Full name of responsible person

Maryam Tahamtan

Position

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Other areas of specialty/work

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