Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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-dimentional transthoracic echocardiography including speckle tracking echocardiography is done using a vivid E9 (General Electric) system and all measurements including LV Ejectin Fraction, Fractional Shortenning, 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
Name
Maryam Tahamtan
Name of organization / entity
Śhiraz Cardiovascular Research Center
Country
Iran (Islamic Republic of)
Phone
+98 71 3628 1562
Email address
mtahamtan@sums.ac.ir

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 Committe 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 recieves 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

Street address

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

City

Shiraz

Postal code

Phone

+98 71 3628 1562

Fax

Email

mtahamtan@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz Cardiovascular Research Center

Full name of responsible person

Maryam Tahamtan

Position

Researcher/Cardiologist

Other areas of specialty/work

Street address

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

City

Shiraz

Postal code

Phone

+98 71 3628 1562

Fax

Email

mtahamtan@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz Cardiovascular Research Center

Full name of responsible person

Maryam Tahamtan

Position

Researcher

Other areas of specialty/work

Street address

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

City

Postal code

Phone

+98 71 3628 1562

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