

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Ejectin 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**

##### **Name**

Maryam Tahamtan

##### **Name of organization / entity**

Shiraz 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 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 Zibaei 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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**Contact**

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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*

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

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