Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

To evaluate the effects of cardiac rehabilitation in patients with recurrence of symptoms after percutaneous coronary intervention (coronary stenting)

Protocol summary

Summary

The aim of this study is to determine the effects of cardiac rehabilitation on the quality of life, functional capacity and maximal exercise capacity in patients with recurrence of symptoms after coronary stenting. Fifty patients who had inclusion criteria, were included randomly in the two groups: intervention (25 people) and control (25 people) after obtaining the informed written consent.Inclusion criteria: recurrence of symptoms(chest pain or dyspnea) after primary coronary stenting.Exclusion criteria: history of coronary artery bypass graft surgery (CABG); functional class 4 according to New York Heart Association(NYHA); severe valvular heart disease; uncontrolled hypertension; uncontrolled diabetes mellitus or thyroid disease; recent myocardial infarction or unstable angina pectoris.The control group continues their routine medications and daily activities, whereas the intervention group participates in cardiac rehabilitation program in addition to continuing their routine medications. Cardiac rehabilitation program continues three times a week for twenty sessions. Each session begins with 5 minutes warm up and stretching exercises and proceeds with intermittent interval training method: 20 seconds with 50% maximal resistance and 40 seconds with 20% of maximal resistance (maximal resistance is measured by ramp test). This method continues up to 20 minutes and ends with 5 minutes cool down and stretching exercises.Total duration of each session is 1 hour(30 minutes for arm exercise and 30 minutes for leg exercise). We will determine the quality of life of all patients, their functional capacity and maximal exercise capacity by the quality of life SF-36 questionnaire, 6 minute walk test(6MWT) and ramp test respectively, in both intervention and control groups at the beginning and end of the study(2 months later).Then the results are compared statistically between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042421921N1**
Registration date: **2015-06-01, 1394/03/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-06-01, 1394/03/11

Registrant information

Name

Fateme Roshanaei Haydarabadi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-03-25, 1394/01/05

Expected recruitment end date

2015-05-26, 1394/03/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
To evaluate the effects of cardiac rehabilitation in patients with recurrence of symptoms after percutaneous coronary intervention (coronary stenting)

Public title
The effects of cardiac rehabilitation in patients with chest pain after coronary stenting
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: The age of forty to seventy years; patients with coronary artery disease that coronary stenting was done for them; recurrence of symptoms (angina or dyspnea) at any time after coronary stenting; ejection fraction: 35% or more; primary stenting.
Exclusion criteria: history of coronary artery bypass graft surgery (CABG); functional class 4 according the New York Heart Association(NYHA); severe valvular heart disease; arrhythmia except atrial fibrillation (without rapid ventricular response); uncontrolled hypertension(systolic blood pressure more than 200 mmHg or diastolic blood pressure more than 120 mmHg); uncontrolled diabetes mellitus or thyroid disease; recent myocardial infarction or unstable angina pectoris; exercise limitation due to neuromuscular, musculoskeletal or mental diseases
Age
From **40 years** old to **70 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)
Not 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
Shiraz University of Medical Sciences, Zand Avenue
City
Shiraz
Postal code
Approval date
2015-03-01, 1393/12/10
Ethics committee reference number
CT-P-9387-8097

Health conditions studied

1

Description of health condition studied
Recurrence of symptoms after percutaneous coronary intervention
ICD-10 code
Z95.5
ICD-10 code description
presence of coronary angioplasty implant and graft

Primary outcomes

1

Description
functional capacity
Timepoint
at the beginning of the study and after 2 months
Method of measurement
distance walked on the 6 min walk test(in meters)

2

Description
maximal exrcise capacity
Timepoint
at the beginning of the study and after 2 months
Method of measurement
maximum workload tolerated by the patient on the ramp test(in watts)

Secondary outcomes

1

Description
quality of life
Timepoint
at the beginning of the study and after 2 months
Method of measurement
Quality of Life SF-36 questionnaire

Intervention groups

1

Description
The intervention group receives cardiac rehabilitation

three times a week for twenty sessions.Each session begins with 5 minutes warm up and stretching exercises and proceeds with intermittent interval training method: 20 seconds with 50% maximal resistance and 40 seconds with 20% of maximal resistance (maximal resistance is measured by ramp test). This method continues up to 20 minutes and ends with 5 minutes cool down and stretching exercises.Total duration of each session is 1 hour(30 minutes for arm exercise and 30 minutes for leg exercise).

Category

Rehabilitation

2

Description

The control group receives no intervention and continues their routine medications and daily activities without any change.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiac Rehabilitation Center of Shahid Faghihi Hospital

Full name of responsible person

Fateme Roshanaei

Street address

Shahid Faghihi Hospital, Zand Avenue, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyyed Basir Hashemi

Street address

Shiraz University of Medical Sciences, Zand Avenue

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Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Fateme Roshanaei

Position

physical medicine and rehabilitation resident

Other areas of specialty/work

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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