

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of exercise-based cardiac rehabilitation after Percutaneous Coronary Interventions (PCIs) on functional capacity and fatigue in patients with coronary heart disease

Protocol summary

Summary

The purpose of this clinical trial is evaluation of the effect of exercise-based cardiac rehabilitation after Percutaneous Coronary Interventions (PCIs) on functional capacity and fatigue in patients with coronary heart disease. Among the study population of patients with coronary heart disease after angioplasty or stenting and referred to cardiac rehabilitation center, 40 patients 35 to 65 years that they have at least three weeks of treatment in the study are. All the patients after the introduction the study and signing written consent, two demographic questionnaire and multidimensional fatigue index (MFI) questionnaire has been completed and 6-minute walk test will be done for them. These patients will be randomized into two groups (20 patients) and control group (20 patients). Patients in the intervention group underwent 24 sessions of cardiac rehabilitation, 3 per week for 8 weeks fall. Each session uses two treadmills and bicycle rehabilitation carried out the 10-15 minute warm-up in the first and 10-15 minutes cool down in the end done and each session lasts approximately one hour. At the end of the session of 12 and 24, fatigue questionnaire completed and 6-minute walk test was done and the end results are analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102924784N1**
Registration date: **2016-02-05, 1394/11/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-05, 1394/11/16

Registrant information

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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology, Yasuj University of Medical Science

Expected recruitment start date

2015-12-06, 1394/09/15

Expected recruitment end date

2016-03-05, 1394/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of exercise-based cardiac rehabilitation after Percutaneous Coronary Interventions (PCIs) on functional capacity and fatigue in patients with coronary heart disease

Public title

the effect of cardiac rehabilitation on functional capacity and fatigue

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age range 65-35 years; do any of the percutaneous coronary intervention (angioplasty and stent insertion) and at least 3 weeks after; the written permission of cardiologist not to ban rehabilitation; ejection fraction greater than or equal (35%); lack of mental disorders; chronic and debilitating respiratory disease and musculo-skeletal disorders; informed consent. Exclusion criteria: patient's lack of motivation to continue working; inability to perform rehabilitation (exercise); absence of more than 3 session of rehabilitation exercises; exacerbation's during the rehabilitation; migration; disease and death.

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Yasuj Univercity of Medical Sciences

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Yasuj Univercity of Medical Sciences, Shahid Motahhari Blvd.

City

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Postal code

7591741417

Approval date

2015-11-24, 1394/09/03

Ethics committee reference number

IR.YUMS.REC.1394.102

Health conditions studied

1

Description of health condition studied

Coronary heart disease

ICD-10 code

I25.9

ICD-10 code description

Chronic ischaemic heart disease, unspecified

Primary outcomes

1

Description

Functional capacity

Timepoint

Before intervention, after 12th session, after 24th session

Method of measurement

6 Minute Walk Test (6MWT)

2

Description

Fatigue

Timepoint

Before intervention, after 12th session, after 24th session

Method of measurement

Multidimensional Fatigue Index (MFI) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the control group: non-implementation of cardiac rehabilitation and reliance on routine management

Category

N/A

2

Description

In the intervention group: 24 session of exercise-base cardiac rehabilitation (3 per week) for an hour each session by using a treadmill and bicycle

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Jahrom Cardiac Rehabilitation Center

Full name of responsible person

Street address

Peymaniyeh hospital, Valiasr St.

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Jahrom

afrasiabifar@yahoo.com

Web page address

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy of Research and Technology, Yasuj University of Medical Sciences

Full name of responsible person

Dr. Mehdi Akbartabar Tori

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Deputy of Research and Technology, Yasuj 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**

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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