

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of a Home-Designed Cardiac Rehabilitation program on blood pressure, heart rate, myocardial oxygen consumption indices and cardiovascular function in patients with coronary artery disease

Protocol summary

Study aim

Effect of a Home-Designed Cardiac Rehabilitation program on blood pressure, heart rate, myocardial oxygen consumption indices and cardiovascular function in patients with coronary artery disease, visiting to Shahid Rahimi hospital in Khorramabad

Design

The subjects of this study are clinical trials with interventional and control groups, two blinds, randomized population.

Settings and conduct

All patients with coronary artery disease referred to Shahid Rahimi hospital in khorramabad city. Following percutaneous coronary angioplasty, in phase IV cardiac rehabilitation. sampling method is a randomized categorical method based on inclusion criteria and available criteria. The eligible individuals are divided into subgroups of morning and evening, and subjects under the floor are randomly assigned to four intervention and control groups Will take.

Participants/Inclusion and exclusion criteria

Inclusion criteria: History of angioplasty, coronary artery disease. Exclusion criteria: At least eight weeks of myocardial infarction and two months of percutaneous coronary angioplasty

Intervention groups

The intervention group received a home cardiac rehabilitation, exercise program, and the necessity of continuing the program. The control groups, also performed the usual cardiac rehabilitation program without utilizing designed program.

Main outcome variables

Blood pressure, heart rate, myocardial oxygen consumption indices and cardiovascular function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181122041725N2**

Registration date: **2020-10-28, 1399/08/07**

Registration timing: **retrospective**

Last update: **2020-10-28, 1399/08/07**

Update count: **0**

Registration date

2020-10-28, 1399/08/07

Registrant information

Name

Mostafa Dehghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3263 0659

Email address

dehghani.m66@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-09, 1399/07/18

Expected recruitment end date

2020-10-21, 1399/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of a Home-Designed Cardiac Rehabilitation program on blood pressure, heart rate, myocardial oxygen consumption indices and cardiovascular function in patients with coronary artery disease

Public title

The effect of home-designed cardiac rehabilitation in patients with coronary artery disease

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

History of angioplasty and angiography At least eight weeks of myocardial infarction and two months of percutaneous coronary angioplasty

Exclusion criteria:

Intraventricular conduction disturbances Ischemic heart disease

Age

From **45 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to control various factors influencing research outcomes, a set of conditions was considered to include subjects in the research. Eligible patients were assigned to the groups through the stratified randomization method. Then, the subjects were selected from the strata through the block randomization method and divided into the intervention and control groups according to the order of the selected block number and the internal arrangement of blocks. The selected block number by luck. It should be noted that to blind the person who performed the sampling and to prevent the prediction of allocation, the size of the blocks was not written in the protocol.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind clinical trial, which the patients were unaware of their allocation to the various groups Moreover, the researcher who was collecting various consequences of interventions will not be aware of group allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Lorestan University of Medical Sciences

Street address

No. 2, Lorestan University of Medical Sciences., Anooshirvan Rezaei Square

City

Korramabad

Province

Lorestan

Postal code

6813833946

Approval date

2020-10-07, 1399/07/16

Ethics committee reference number

IR.LUMS.REC.1397.105

Health conditions studied

1

Description of health condition studied

Effect of program designed cardiac rehabilitation in percutaneous coronary angioplasty

ICD-10 code

I25.7

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris

Primary outcomes

1

Description

Blood pressure

Timepoint

Before and after 8 weeks of cardiac rehabilitation

Method of measurement

Blood pressure device

2

Description

Heart rate

Timepoint

Before and after 8 weeks of cardiac rehabilitation

Method of measurement

Electrocardiogram

3

Description

Myocardial oxygen consumption

Timepoint

Before and after 8 weeks of cardiac rehabilitation

Method of measurement

Exercise test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group carried out the cardiac rehabilitation walking program using pedometers. The pedometer feedback- based home cardiac rehabilitation program in this research included walking at home for almost 45-60 min (5-min warm-up, 40- min walking, and 5- min cool-down and stretching exercises).

Category

Rehabilitation

2

Description

Control group: The control group also performed the usual cardiac rehabilitation program without utilizing pedometer feedback. The control group had the same cardiac rehabilitation exercise program but did not use the step counter feedback.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rahimi hospital city Khorramabad

Full name of responsible person

Mostafa dehghani

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No. 1, Mojahedin Street., Azadi Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Ebrahim fallahi

Street address

No. 2, Lorestan University of Medical Sciences.,
Anooshirvan Rezaei Square

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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

Khoram-Abad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Mostafa dehghani

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only part of the data, such as the original outcome information

When the data will become available and for how long

1399

To whom data/document is available

Researchers working in academia and scientific

Under which criteria data/document could be used

researchers

From where data/document is obtainable

Telephone

What processes are involved for a request to access data/document

Phone numbers, or email addresses, along with the names and addresses of individuals

Comments