

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigation and comparison of clinical status improvement following an exercise rehabilitation period in cardiac patients after right coronary artery (RCA) or left anterior descending coronary artery (LAD) angioplasty.

Protocol summary

Study aim

This research aims to compare the effectiveness of a sports rehabilitation course on improving the clinical condition in cardiac patients who have experienced coronary artery angioplasty.

Design

Non-randomized trial with non-blinded postoperative care and outcome assessment. Trial with a parallel group design of 30 patients, enrolled between July 2023 and September 2023.

Settings and conduct

A clinical trial will involve an 8-week rehabilitation program at Hamedan Farshchian Hospital's Cardiac Rehabilitation Center. Participants will attend three sessions per week for a total of 24 sessions.

Participants/Inclusion and exclusion criteria

Two groups of 15 patients will be studied after performing right coronary artery (RCA) and left coronary artery (LAD) angioplasty, who refer to the cardiac rehabilitation department of Farshchian Heart and Vascular Hospital in Hamedan.

Intervention groups

Training session includes aerobic exercise based on individual capacity, followed by light resistance exercises using body weight and dumbbells. Cooling down at the end helps prevent reflexes. It is necessary to explain that in the aerobic training section, each person will train with a treadmill, foot ergometer, and manual ergometer.

Main outcome variables

Quality of Life, Respiratory efficiency, Cardiovascular function, Prevalence rate of myocardial infarction, coronary angioplasty, angina pectoris, and Coronary artery reocclusion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230501058035N1**

Registration date: **2023-05-23, 1402/03/02**

Registration timing: **prospective**

Last update: **2023-05-23, 1402/03/02**

Update count: **0**

Registration date

2023-05-23, 1402/03/02

Registrant information

Name

Ramin Mansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 939 013 1815

Email address

raminmn4@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-21, 1402/03/31

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigation and comparison of clinical status improvement following an exercise rehabilitation period in cardiac patients after right coronary artery (RCA) or left anterior descending coronary artery (LAD) angioplasty.

Public title
Investigation improvement following an exercise rehabilitation period in cardiac patients after angioplasty.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who have undergone coronary artery angioplasty and refer to the cardiac rehabilitation department
Exclusion criteria:
The patient has not undergone valve repair surgeries. Absence of severe heart failure. Absence of movement problems and debilitating environmental joint diseases, and severe skeletal disorders Absence of debilitating cognitive disorders No history of heart or thorax surgery Not involving more than one coronary vessel in angioplasty No history of congenital heart problems The patient does not have pericardial perfusion experience.

Age
From **40 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not 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

Ethics committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh st, Hamadan, Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

6517838736

Approval date

2023-05-11, 1402/02/21

Ethics committee reference number

IR.UMSHA.REC.1401.475

Health conditions studied

1

Description of health condition studied

cardiac patients after coronary artery

ICD-10 code

Z95.5

ICD-10 code description

Presence of coronary angioplasty implant and graft

Primary outcomes

1

Description

The percentage of heart patients who underwent coronary artery angioplasty.

Timepoint

The systolic and diastolic function of the heart's left ventricle will be measured in two stages (before the beginning of the training period and after its completion).

Method of measurement

Using an echocardiography device using the Simpson method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The said test consists of seven stages of three minutes. The first stage starts with a treadmill slope of 10%, and in each stage, 2% is added to the slope. Also, the treadmill's speed in the first stage is 2.74 km/h, which increases increasingly in the later stages. In sports training sessions, each session will begin with a standard warm-up phase, which includes 5 minutes of light-intensity activity and static and dynamic stretching exercises. The main part of the training session consists of two separate parts. In the aerobic exercise section, each person exercises with moderate intensity (Met 3-6 or pressure perception scale 12-13 on the 15-value Borg scale) according to his maximum aerobic capacity obtained in the test. In the second part

of the training session, after the aerobic exercise, light resistance exercises using body weight and dumbbells are performed for the patients by the physiotherapist. At the end of the training session, cooling is adopted to prevent parasympathetic reflexes. It is necessary to explain that in the aerobic training section, each person will train alternately in three sessions a week with a treadmill, foot ergometer, and manual ergometer. The exercises will be carried out three days a week and finally for eight weeks.

Category

Rehabilitation

2

Description

Intervention group: The said test consists of seven stages of three minutes. The first stage starts with a treadmill slope of 10%, and in each stage, 2% is added to the slope. Also, the treadmill's speed in the first stage is 2.74 km/h, which increases increasingly in the later stages. In sports training sessions, each session will begin with a standard warm-up phase, which includes 5 minutes of light-intensity activity and static and dynamic stretching exercises. The main part of the training session consists of two separate parts. In the aerobic exercise section, each person exercises with moderate intensity (Met 3-6 or pressure perception scale 12-13 on the 15-value Borg scale) according to his maximum aerobic capacity obtained in the test. In the second part of the training session, after the aerobic exercise, light resistance exercises using body weight and dumbbells are performed for the patients by the physiotherapist. At the end of the training session, cooling is adopted to prevent parasympathetic reflexes. It is necessary to explain that in the aerobic training section, each person will train alternately in three sessions a week with a treadmill, foot ergometer, and manual ergometer. The exercises will be carried out three days a week and finally for eight weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiology subspecialty medical center Farshchian

Full name of responsible person

Amirhossein Yazdi

Street address

Shahid Fahmideh Ave., Hamadan Town, Iran

City

Hamadan

Province

Hamadan

Postal code

6517839131

Phone

+98 81 3838 1740

Email

hcvc@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokoohi

Street address

School of Health, Health Sciences Research Center, Hamadan University of Medical Sciences, Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Phone

+98 81 3131 4058

Email

reza.shokohi@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Amir Hossein Yazdi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Farshchian Cardiovascular Subspecialty Medical Center, Shahid Fahmideh Ave, Hamadan City, Iran

City

Hamadan
Province
Hamadan
Postal code
6517839131
Phone
+98 81 3838 1740
Email
amirhoseyn.yazdi@umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Lobat Majidi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
Street address
Farshchian Cardiovascular Subspecialty Medical Center, Shahid Fahmideh Ave, Hamadan City, Iran
City
Hamadan
Province
Hamadan
Postal code
6517839131
Phone
+98 918 315 8983
Email
l.majidi@umsha.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Zahra Shaghaghi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Nuclear Medicine
Street address
Farshchian Cardiovascular Subspecialty Medical Center, Shahid Fahmideh Ave, Hamadan City, Iran

City
Hamadan
Province
Hamadan
Postal code
6517839131
Phone
+98 81 3838 1740
Email
z.shaghaghi@umsha.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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 a part of the data, such as the information related to the main outcome or the like, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Our data will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Our data will be available to all scientific researchers who request via official email.

From where data/document is obtainable

z.shaghaghi@umsha.ac.ir via email

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

Researchers will receive the data by sending a data access request six months after the article's publication by sending an email to z.shaghaghi@umsha.ac.ir.

Comments