

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

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#### 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

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

Hamedan University of Medical Sciences

**Full name of responsible person**

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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**

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

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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## 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