

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of Exercise-based Cardiac Rehabilitation on the volume and size of heart valves and quality of life in myocardial infarction patients with during the COVID-19 pandemic period

Protocol summary

Study aim

The effect of Exercise-based Cardiac Rehabilitation on the volume and size of heart valves and quality of life in myocardial infarction patients with during the COVID-19 pandemic period.

Design

A clinical trial with a control group, with parallel groups and a sample size of 150 people, single blind, randomized, and the "simple random allocation" method was used for randomization.

Settings and conduct

In this study, the intervention group program included supervised aerobic walking on a flat surface (which was monitored using a smart wristband, Xiaomi Mi Band 4, China), push-up & sit-ups, as well as follow-up phone calls, for eight weeks (three sessions per week) [In Cardiovascular Research Center Shahid Rahimi Hospital Khorramabad] and evaluated for major outcomes. The control group received routine care without supervision during the same period. The study is a single blind study that physician and patient are aware of what kind of rehabilitation is being done for the patient, but the statistical analyzer was blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: History of myocardial infarction.

Exclusion criteria: At least eight weeks of myocardial infarction.

Intervention groups

The intervention group program, included supervises exercise and walking (monitored via smart wristbands), as well as follow-up phone calls, for eight weeks (three sessions per week). The control group receives routine care without supervision during the same period.

Main outcome variables

left ventricular end-systolic and end-diastolic dimension, left ventricular end-systolic and end-diastolic volume

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181122041725N4**

Registration date: **2022-09-12, 1401/06/21**

Registration timing: **retrospective**

Last update: **2022-09-12, 1401/06/21**

Update count: **0**

Registration date

2022-09-12, 1401/06/21

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

2022-07-29, 1401/05/07

Expected recruitment end date

2022-08-03, 1401/05/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Exercise-based Cardiac Rehabilitation on the volume and size of heart valves and quality of life in myocardial infarction patients with during the COVID-19 pandemic period

Public title

The effect of cardiac rehabilitation in patients with myocardial infarction during the COVID-19

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

History of myocardial infarction

Exclusion criteria:

Severe aortic stenosis Suffering from nervous and mental illness

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

First, we talk to patients who have indications for rehabilitation about the advantages and disadvantages of both home rehabilitation and in-hospital rehabilitation methods and then Patients who have the basic conditions for both methods of rehabilitation will be randomized. Eligible patients were assigned to the intervention and control groups through the block randomization method. In this method, treatment blocks are arranged randomly with letters A and B. And we use blocks of 3, 6 and 4, so that the size of the tiles is the same. And by putting the random blocks together, we will create a balanced random list of two treatment groups, and until the sample size of the two groups is filled, random allocation will continue using the above blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, blindness was performed in a single blind method and the physician (researcher) and the patient are aware of what kind of rehabilitation is being done for the patient, but the statistician does not know which patient is being rehabilitated at supervised exercise And which of the patients was rehabilitated in the routine care.

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

خرم آباد

Province

Lorestan

Postal code

6813833946

Approval date

2022-07-27, 1401/05/05

Ethics committee reference number

IR.LUMS.REC.1401.118

Health conditions studied

1

Description of health condition studied

Effect of program cardiac rehabilitation in myocardial infarction

ICD-10 code

I22.9

ICD-10 code description

Subsequent ST elevation (STEMI) myocardial infarction of unspecified site

Primary outcomes

1

Description

Left ventricular end-systolic and end-diastolic dimension

Timepoint

Before and after 3 month of cardiac rehabilitation

Method of measurement

Echocardiography device

2

Description

Left ventricular end-systolic and end-diastolic volume

Timepoint

Before and after 3 month of cardiac rehabilitation

Method of measurement

Echocardiography device

Secondary outcomes

1

Description

Stroke volume

Timepoint

Before and after 3 month of cardiac rehabilitation

Method of measurement

Echocardiography device

Intervention groups

1

Description

Intervention group: The intervention group program, included supervises exercise and walking (monitored via smart wristbands), as well as follow-up phone calls, for 3 month (three sessions per week).

Category

Rehabilitation

2

Description

Control group: The control group also perform the usual cardiac rehabilitation program recommendations by the physician to walk 40 minutes (three sessions per week), but they did not have any supervised exercise training during this period. During the study, all the participants (the intervention and control groups) receive their usual medications.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiovascular Research Center of Shahid Rahimi
Khorramabad Hospital

Full name of responsible person

Mostafa dehghani

Street address

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

Bahram Rasoulia

Street address

No. 2, Lorestan University of Medical Sciences.,
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rasoulia@irimc.org

Grant name

Grant code / Reference number

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

No

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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No. 7, West Kakavand Street., Alavi Square

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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

All potential data can be shared after unidentifiable people

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academia and scientific

Under which criteria data/document could be used

The necessary condition for submitting a request for access to data or documentation of the use of data for the purposes of protection, treatment of patients.

From where data/document is obtainable

Cardiovascular research center shahid Rahimi Hospital
korramabad, Mostafa Dehghani
Dehghani.m66@gmail.com

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

The applicant will receive the document within one week of the request by email.

Comments