Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 66 3263 0659

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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 Rasoulian
Street address
No. 2, Lorestan University of Medical Sciences., Anooshirvan Rezaei Square
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6814664535
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rasoulian@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

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Position
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Other areas of specialty/work
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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