Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effectiveness of Cardiac Rehabilitation based on High-volume (HV-HIIT) and low-volume (LV-HIIT) High-Intensity Interval Training on Serum levels of some miRNAs, myocardial contractile biomarkers , Inflammatory and Functional Markers in Myocardial Infarction Patients

Protocol summary

Study aim

Compared the Effectiveness of High -volume vs low-volume High-Intensity Interval Training in Myocardial Infarction Patients.

Design

The study is a randomized controlled clinical trial with a control group, doubl-blind, three-arm, parallel-groups, phase 2 on 128 patients, Randomized by block and stratified method with a randomization ratio of 1: 1: 1.

Settings and conduct

Place of study: The trial will be conducted in theCardiovascular Therapy Clinic (Healthy Heart Rehabilitation Center) , Khorramabad , Lorestan. Blinding type: doubl-blind. How blinding: Medical staff will be blinded to participant randomization assignment.Both participants and outcome assessors are unaware of the allocation of study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: MI type I; At least Six months to two years after diagnosis and angioplasty; 45≤ Age ≤60 years; clinically stable on sinus rhythm; Left ventricular ejection fraction > 40% . Exclusion criteria: Unstable coronary artery disease; uncontrolled hypertension; malignant ventricular arrhythmia; exercise-induced ischemia.

Intervention groups

Intervention group 1: high-volume HIIT training for 40 minutes. Intervention group 2: low-volume HIIT training for 20 minutes. control group: physical activity recommendations.

Main outcome variables

Serum levels of miR-1, miR208,miR-133, mRNA Caspas3, ontractile biomarkers, inflammatory markers, cardiac function Indicators, quality of life.

General information

Reason for update

Change the sample size, add the number of dependent variables

Acronym

IRCT registration information

IRCT registration number: **IRCT20201022049111N1**
Registration date: **2020-11-29, 1399/09/09**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-21, 1401/02/01**
Update count: **1**

Registration date

2020-11-29, 1399/09/09

Registrant information

Name

zohreh delfani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 4230 8790

Email address

venus_delfani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-19, 1399/08/29

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

2020-11-18, 1399/08/28

Actual recruitment end date

2021-07-21, 1400/04/30

Trial completion date

2021-11-20, 1400/08/29

Scientific title

Comparison of the Effectiveness of Cardiac Rehabilitation based on High- volume (HV-HIIT) and low-volume (LV-HIIT) High-Intensity Interval Training on Serum levels of some miRNAs, myocardial contractile biomarkers , Inflammatory and Functional Markers in Myocardial Infarction Patients

Public title

Effect of High-Intensity Interval Training on Cardiac Rehabilitation among Myocardial Infarction Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

MI type 1 and having an ejection fraction of 40% At least six to two years have passed since the diagnosis and angioplasty Be in a stable condition without drug changes In class II, I have cardiac function. Maximum metabolic equivalent to or more than 5 MET

Exclusion criteria:

Metabolic diseases such as diabetes and obesity Variable blood pressure Congestive heart failure Dangerous arrhythmias Liver and kidney failure Chronic obstructive pulmonary disease Neuromuscular disorders

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **128**

Actual sample size reached: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization will be the permuted block randomization (42patients per block) with stratification based on age and sex.A random allocation sequence list will be generated using a web-based app, that is, Random.org.An independent research assistant who did not participate in any other parts of the research will be generated and maintained the random allocation sequence list. This independent research assistant will assign group labels to the participants according to the sequence of their entry, referring to the random allocation sequence list to ensure that the other members of the research team did not foresee the group allocation. Allocation concealment will be performed by sequentially numbered sealed opaque envelopes. independent research assistant generated the random allocation sequence and distributed these in serially numbered sealed opaque envelopes. Envelopes will be opened in a sequential manner (serial number in participant list and serial number mentioned on top of envelope will be the same in all cases) in the presence of the participant and a witness (usually family member of the participant), and intervention allocation will be implemented accordingly.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be double-blind. Medical staff will be blinded by the random assignment of participants in study groups. The assignment will be performed by a sports physiologist who is not involved in the testing process. Both participants and researchers or outcome assessors are unaware of the assignment of study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Clinical Investigation of Lorestan University of Medical Sciences

Street address

Lorestan University of Medical Sciences, Shahid Anooshirvan Rezaei square, Moallem street

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2019-11-08, 1398/08/17

Ethics committee reference number

IR.LUMS.REC.1398.254

2

Ethics committee

Name of ethics committee

Ethics Committee of Clinical Investigation of Lorestan University of Medical Sciences

Street address

Lorestan University of Medical Sciences, Shahid Anooshirvan Rezaei square, Moallem street

City

Khorramabad

Province

Lorestan

Postal code
6813833946
Approval date
2020-10-06, 1399/07/15
Ethics committee reference number
IR.LUMS.REC.1399.198

Health conditions studied

1

Description of health condition studied
Myocardial infarction
ICD-10 code
I25
ICD-10 code description
Chronic ischemic heart disease

Primary outcomes

1

Description
Expression of miR-1
Timepoint
Before and after the intervention
Method of measurement
Real time – PCR

2

Description
C-Reactive Protein (CRP)
Timepoint
Before and after the intervention
Method of measurement
by using the immunometric assay technique method and ELISA Kit

3

Description
Uric acid
Timepoint
Before and after the intervention
Method of measurement
by using the immunometric assay technique method and ELISA Kit

4

Description
Expression of miR-208
Timepoint
Before and after the intervention
Method of measurement
Real time – PCR

5

Description
Expression of miR-133
Timepoint
Before and after the intervention
Method of measurement
Real time – PCR

6

Description
Expression of mRNACapas3
Timepoint
Before and after the intervention
Method of measurement
Real time – PCR

7

Description
CK-mb
Timepoint
Before and after the intervention
Method of measurement
by using the immunometric assay technique method and ELISA Kit

8

Description
Troponin
Timepoint
Before and after the intervention
Method of measurement
by using the immunometric assay technique method and ELISA Kit

Secondary outcomes

1

Description
Quality of Life
Timepoint
Before and after the intervention
Method of measurement
Quality of Life Questionnaire

2

Description
Ejection fraction
Timepoint
Before and after the intervention
Method of measurement
Echocardiography and Simpson

3

Description
Systolic blood pressure
Timepoint
Before and after the intervention
Method of measurement
Digital blood pressure device

4

Description
Maximal Oxygen Consumption (peak VO2)
Timepoint
Before and after the intervention
Method of measurement
Exercise stress test

5

Description
End-systolic volume
Timepoint
Before and after the intervention
Method of measurement
M-mode echocardiography

6

Description
diastolic blood pressure
Timepoint
Before and after the intervention
Method of measurement
Digital blood pressure device

7

Description
End-Diastolic volume
Timepoint
Before and after the intervention
Method of measurement
M-mode echocardiography

Intervention groups

1

Description
Intervention group 1 (HV-HIIT group): A training session on the treadmill at 4 × 4-minute intervals at 90% of HRr with 3 minutes of active recovery at 65% of HRr between intervals and a training session on the bike with 16× 30 seconds intervals with 60 seconds of active recovery at 65% of HRr between intervals , with total exercise of 40 minutes/session.
Category
Rehabilitation

2

Description
Intervention group2 (LV-HIIT group): A training session on the treadmill with two 4-minute intervals at an interval intensity of ~85% HRr with 3 minutes of active recovery at 65% of HRr between intervals and a training session on the bike with 8× 30 seconds intervals with 60 seconds of active recovery at 70% of HRr between intervals, with total exercise of 20 minutes/session
Category
Rehabilitation

3

Description
Control group: The control group will receive regular physical exercise recommendations to keep ethical procedures regarding health. In this sense, participants will be advised to participate, without supervision, in at least 30 min of moderate-intensity dynamic aerobic exercise (walking, jogging, cycling, or swimming) 5–7 days per week.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani hospital
Full name of responsible person
Mostafa Cheraghi
Street address
Shahid Madani hospital., West Shahid Beheshti (Khairabad) street, Imam Hossein square
City
Khorramabad
Province
Lorestan
Postal code
6813833946
Phone
+98 66 3333 6150
Email
pr@lums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Mahnaz Samadbek
Street address
Lorestan University of Medical Sciences, Shahid Anooshirvan Rezaei square, Moallem street
City
Khorramabad
Province
Lorestan
Postal code
381251698
Phone
+98 66 3312 0173
Email
research@lums.ac.ir
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

50

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

Mustafa Cheraghi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

Street address

Lorestan University of Medical Sciences, Shahid Anooshirvan Rezaei square, Moallem street

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Dcheraghi406@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Mustafa Cheraghi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Mustafa Cheraghi

Position

Associate professor

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some of the data on the main outcome can be shared after people are not identified.

When the data will become available and for how long

Starting available 6 months after the publication of results

To whom data/document is available

Only for researchers working in academic and scientific institutions will be available.

Under which criteria data/document could be used

Only for meta-analysis research

From where data/document is obtainable

Dr. Mostafa Cheraghi.,Cardiovascular Research Center.,Lorestan University of Medical Sciences.

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

Written and co-ordination of the organs of the Cardiovascular Research Center, Lorestan University of Medical Sciences

Comments