

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of two different high-intensity interval training on clinical status improvement after coronary artery bypass grafting in cardiac patients

Protocol summary

Study aim

Comparison of the effect of two different high-intensity interval training on clinical status improvement after coronary artery bypass grafting in cardiac patients

Design

A clinical trial with the control group, parallel groups, double-blind, block randomization, 99 patient as a sample size

Settings and conduct

The purpose of this study is to evaluate the efficacy of two types of high-intensity interval aerobic exercise on improving the clinical status of cardiac patients after coronary artery bypass surgery using a control group. The location is Farshchian Cardiovascular Hospital. The study is a double-blind in which participants, researchers, clinical caregivers, outcome assessors, and data analyzers were blinded. Clinical measurements will also be performed before and after the training period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. The patient undergoes a coronary artery bypass grafting surgery 2. The age of the patient must be between 40-80 years old Exclusion criteria: 1. The patient should not undergo reconstructive heart valve injury 2. The patient should not have disabling movement disorders

Intervention groups

1. Control group that performs the routine exercise program of the hospital rehabilitation center 2. High-intensity interval training group with short-time active intervals 3. High-intensity interval training group with mid-time active intervals

Main outcome variables

Maximal aerobic power, Systolic and diastolic function of cardiac left ventricle, Heart rate variability, Quality of life, Lower extremity muscle strength

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200113046119N1**

Registration date: **2020-04-11, 1399/01/23**

Registration timing: **prospective**

Last update: **2020-04-11, 1399/01/23**

Update count: **0**

Registration date

2020-04-11, 1399/01/23

Registrant information

Name

Reza Ghahremani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two different high-intensity interval training on clinical status improvement after coronary artery bypass grafting in cardiac patients

Public title

Investigation of the effect of exercise training on clinical status in infarction cardiac patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The age of the subjects must be between 40-80 years old-age The subjects must undergo the coronary artery bypass grafting surgery

Exclusion criteria:

There are disabling motor disorders in the patient The patient undergoes reconstructive valve surgery

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization is used in the current study. The randomization unit is also considered individual. The random number table is also used as a randomization tool.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blinded that the subjects, clinical caregivers, researchers, outcome evaluators, and data analyzers are unaware of the allocation of study groups. Of course, The overall introduction of the study groups has been completely provided to the participants.

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 Ave

City

Hamadan

Province

Hamadan

Postal code

65178

Approval date

2019-10-07, 1398/07/15

Ethics committee reference number

IR.UMSHA.REC.1398.310

Health conditions studied

1

Description of health condition studied

Coronary artery disease

ICD-10 code

I25

ICD-10 code description

Chronic ischemic heart disease

Primary outcomes

1

Description

Maximal aerobic power

Timepoint

Before and after the treatment

Method of measurement

Bruce treadmill test

2

Description

Heart rate variability

Timepoint

Before and after the treatment

Method of measurement

Electrocardiogram assessment of the patient

3

Description

Quality of life

Timepoint

Before and after the treatment

Method of measurement

Heart disease patient's questionnaire

4

Description

Lower extremity muscle strength

Timepoint

Before and after the treatment

Method of measurement

One repetition maximum test of the leg press

5

Description

Systolic and diastolic function of cardiac left ventricle

Timepoint

Before and after the treatment

Method of measurement

Echocardiography

Secondary outcomes

1

Description

Resting heart rate of the patient

Timepoint

Before and after the treatment

Method of measurement

Polar heart rate monitoring

2

Description

Recovery heart rate of the patient

Timepoint

Before and after the treatment

Method of measurement

Polar heart rate monitoring

3

Description

Blood pressure

Timepoint

Before and after the treatment

Method of measurement

Mercury manometer

4

Description

Body composition of the patient

Timepoint

Before and after the treatment

Method of measurement

Body composition analyzer

Intervention groups

1

Description

First intervention group: High-intensity interval training Group with Short Activity Interventions: This group will perform high-intensity interval training exercises with 15-second intervals on the treadmill for 12 weeks and 24 training sessions. Indeed, there will be two training

sessions in a week. The group's training program involves 15-second activity intervals with the intensity of 100% maximal aerobic power, with 15-second passive recovery among them. Each training session continues for 35 minutes.

Category

Rehabilitation

2

Description

Control group: This group will participate in the routine rehabilitation program of the Hamadan Farshchian Hospital for 12 weeks and 24 training sessions. Indeed, there will be two training sessions in a week. Each training session continues for 35 minutes. The group's training program involves aerobic continuous moderate-intensity training on the treadmill.

Category

Rehabilitation

3

Description

Second intervention group: High-intensity interval training Group with intermediate Activity Interventions: This group will perform high-intensity interval training exercises with 60-second intervals on the treadmill for 12 weeks and 24 training sessions. Indeed, there will be two training sessions in a week. The group's training program involves 60-second activity intervals with the intensity of 100% maximal aerobic power, with 60-second passive recovery among them. Each training session continues for 35 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian hospital

Full name of responsible person

Lobat Majidi

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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

Lobat Majidi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable