

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparative Effectiveness of Two Cardiac Rehabilitation Approaches in Middle-Aged and Elderly Men with Coronary Artery Disease

Protocol summary

Study aim

1. Evaluate effects of 8-week aerobic exercise on cardiac function in elderly men post-myocardial infarction.
2. Assess effects of 8-week aerobic-resistance exercise on cardiac function in the same group.
3. Compare effects of aerobic vs. aerobic-resistance exercise on cardiac variables in elderly men after myocardial infarction

Design

This applied, semi-experimental study uses a pre-post design to compare the effects of aerobic and aerobic-resistance training on cardiovascular outcomes in men with coronary artery disease.

Settings and conduct

The study is conducted at Modares Hospital, Tehran, on men aged 45–65 with coronary artery disease. After medical clearance, the training and assessments are carried out before and after the 8-week intervention.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Men 45–65 years, healthy or with coronary artery disease/post-heart procedures, medically cleared, non-smokers, and no recent alcohol use.

Exclusion Criteria: Cardiac warning signs during exercise, chronic disabling diseases, or lower limb disabilities preventing exercise.

Intervention groups

Aerobic Group: 3 weekly sessions of aerobic exercise (cycling, elliptical) at 50–80% max heart rate with warm-up and cool-down, intensity increasing over 8 weeks; vital signs monitored. Aerobic-Resistance Group: Same aerobic protocol plus 2 weekly resistance sessions (30–50% 1RM, 12–15 reps).

Main outcome variables

1. Systolic Blood Pressure,
2. Diastolic Blood Pressure,
3. Resting Heart Rate,
4. Left Ventricular Systolic Function,
5. Cardiac Capacity and Performance

General information

Reason for update

Acronym

Cardiac Rehabilitation/Secondary Prevention (CRSP)

IRCT registration information

IRCT registration number: **IRCT20250603066054N1**

Registration date: **2025-06-20, 1404/03/30**

Registration timing: **prospective**

Last update: **2025-06-20, 1404/03/30**

Update count: **0**

Registration date

2025-06-20, 1404/03/30

Registrant information

Name

Heydar Sadeghi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-06, 1404/04/15

Expected recruitment end date

2025-09-01, 1404/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Effectiveness of Two Cardiac Rehabilitation Approaches in Middle-Aged and Elderly Men with Coronary Artery Disease

Public title

Considering the effect of Two Cardiac Rehabilitation Approaches in Middle-Aged and Elderly Men with Coronary Artery Disease

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Middle-aged men (45-65 years) with myocardial infarction Physician's approval for participation in the exercise program Non-smokers No alcohol consumption

Exclusion criteria:

Presence of warning signs during exercise Unstable angina pectoris Dyspnea at rest or severe arrhythmias Chronic diseases causing discomfort during exercise ST segment elevation or depression on ECG during exercise Respiratory disturbances during exercise Inability or unwillingness to complete the exercise program

Age

From **45 years** old to **65 years** old

Gender

Male

Phase

2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

This study used a randomized controlled trial design. Thirty-two men with coronary artery disease were randomly assigned to two intervention groups: aerobic training and concurrent (combined) training. Participants were stratified by age (middle-aged and elderly) and then randomly allocated within each stratum using a simple randomization method. Randomization was conducted by an independent researcher using a random number table. Allocation concealment was maintained through coded identifiers, and outcome assessors were blinded to group assignments.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention (supervised exercise training), blinding of participants, care providers, and investigators was not feasible. However, outcome assessors and data analysts were blinded to group allocation to minimize detection and analysis bias. This single-blind approach helped ensure objectivity in data evaluation and result interpretation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Kharazmi University Ethics Committee

Street address

Kharazmi University, Shahid Haghani Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

15719-14911

Approval date

2025-06-01, 1404/03/11

Ethics committee reference number

IR.KHU.REC.1404.039

Health conditions studied**1****Description of health condition studied**

Cardiovascular disease including myocardial infarction in men aged 45 to 65

ICD-10 code

ICD-10: I2

ICD-10 code description

Ischemic heart diseases (I20-I25)

Primary outcomes**1****Description**

Primary outcomes include changes in systolic and diastolic blood pressure, resting heart rate, left ventricular ejection fraction, and cardiac capacity and performance as assessed by stress testing, measured before and after the 8-week intervention.

Timepoint

Primary outcome variables will be measured at two time points: baseline (before the intervention) and immediately after the 8-week exercise program.

Method of measurement

Systolic Blood Pressure: Measured using a blood pressure monitor in mmHg. Diastolic Blood Pressure: Measured using a blood pressure monitor in mmHg. Resting Heart Rate: Measured by counting heartbeats per minute at rest. Left Ventricular Systolic Function: Calculated by echocardiography using ejection fraction (stroke volume/end-diastolic volume). Cardiac Capacity and

Performance: Assessed using a cardiac stress test (exercise test).

Secondary outcomes

empty

Intervention groups

1

Description

Aerobic Exercise Group: Three weekly sessions of aerobic training including warm-up, main activities (cycling and elliptical at 50-80% max heart rate), and cool-down, with gradual increase over 8 weeks. Aerobic-Resistance Exercise Group: Same aerobic protocol plus two weekly resistance training sessions targeting major muscle groups at 30-50% one-rep max, 12-15 reps.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Modares Hospital

Full name of responsible person

Reza Arefizadeh

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Army University of Medical Sciences (AJA), Shahid Etemadzadeh St, West Fatemi Ave, Tehran 14356, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Self-funded by the investigators

Full name of responsible person

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Web page address

Grant name

Supervisor's funding

Grant code / Reference number

none

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

No

Title of funding source

Supervisor's funding

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Kharazmi University

Full name of responsible person

Heydar.Sadeghi

Position

Full Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

No - There is not 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

Title: Clinical Trial Data on Cardiac Rehabilitation in Middle-Aged and Elderly Men with Coronary Artery Disease Details: This dataset includes de-identified participant data collected during pre- and post-intervention phases of the cardiac rehabilitation study, including demographic information, physiological measurements (blood pressure, heart rate, echocardiography results), and exercise protocol details.

When the data will become available and for how long

The data will be available starting 6 months after the publication of the study results. The dataset will remain accessible for a minimum of 5 years through an online data repository.

To whom data/document is available

Available to researchers upon request

Under which criteria data/document could be used

The data will be available for academic and research purposes only. Users must agree to a data use agreement ensuring confidentiality and ethical use. Access to the data will be granted after approval by the principal investigator. Additional note: If the journal requests, the data and related documents will be made available to the journal editors and reviewers upon reasonable request to verify the study findings.

From where data/document is obtainable

Data and documents will be available from the corresponding author upon reasonable request.

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

Interested researchers should submit a formal request via email to the corresponding author detailing the purpose of data use. The request will be reviewed by the principal investigator for approval. Upon approval, a data use agreement ensuring confidentiality and ethical use must be signed. After completing these steps, access to data/documents will be granted.

Comments

No additional comments.