Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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

Department of Biomechanics and Sports Injury, Faculty of Physical Education and Sports Sciences, Kha

Country

Iran (Islamic Republic of)

Phone

+98 912 245 3175

Email address

h.sadeghi@khu.ac.ir

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
Street address
Army University of Medical Sciences (AJA), Shahid Etemadzadeh St, West Fatemi Ave, Tehran 14356, Iran
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 912 928 2729
Email
r.arefizadeh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Self-funded by the investigators
Full name of responsible person
Heydar Sadeghi
Street address
Faculty of Physical Education and Sport Sciences, Kharazmi University, End of Southern Razan (Shahid Hessari) Street, next to Shahid Keshvari Sports Complex, Mohseni (Mirdamad) Square, Mirdamad Blvd., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
3311115447
Phone
+98 912 245 3175
Fax
Email
h.sadeghi@khu.ac.ir
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
Department of Biomechanics and Sports Pathology
Street address
Faculty of Physical Education and Sport Sciences, Kharazmi University, End of Southern Razan (Shahid Hessari) Street, next to Shahid Keshvari Sports Complex, Mohseni (Mirdamad) Square, Mirdamad Blvd., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
3311115447
Phone
0212228001
Email
h.sadeghi@khu.ac.ir

Person responsible for scientific 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
2. Department of Biomechanics and Sports Pathology

Street address
Faculty of Physical Education and Sport Sciences, Kharazmi University, End of Southern Razan (Shahid Hessari) Street, next to Shahid Keshvari Sports Complex, Mohseni (Mirdamad) Square, Mirdamad Blvd., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
3311115447

Phone
+98 21 2222 8001

Email
h.sadeghi@khu.ac.ir

Person responsible for updating data

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
2. Department of Biomechanics and Sports Pathology

Street address
Faculty of Physical Education and Sport Sciences, Kharazmi University, End of South Razan Street (Shahid Hesari), near Shahid Keshvari Sports Complex, Mirdamad Boulevard, Mohseni Square, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1544733111

Phone
+98 21 2222 8001

Email
h.sadeghi@khu.ac.ir

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.