Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effect of Eight Weeks Aerobic and Combined Exercise on Hemodynamic, Hemorheological, Structural and Functional indicators of the Heart in Middle-Aged Male Patients Undergoing Coronary Artery Bypass Graft

Protocol summary

Study aim
Comparison of the Effect of Eight Weeks Aerobic and Combined Exercise on Hemodynamic, Hemorheological, Structural and Functional indicators of the Heart in Middle-Aged Male Patients undergoing Coronary Artery Bypass Graft Surgery.

Design
The Cinical trial has Aerobic, Combination and Control groups, a blind strain, randomized on 30 patients. A simple lottery method was used for randomization.

Settings and conduct
Exercises will be performed in Imam Ali Hospital, Kermanshah, three sessions a week for eight weeks and each session will be 1 hour. Without knowing the study group, the subject is placed in a special group by lottery and random.

Participants/Inclusion and exclusion criteria
Middle-aged male patients undergoing coronary artery surgery Inclusion criteria: men, coronary artery surgery within the previous 8 weeks, heart contractility greater than 40%, surgery by a single surgeon and echocardiography by a single cardiologist, not smoking for at least three months. Exclusion criteria from the study: Musculoskeletal disease, sports activity outside of the study program, absence of more than two sessions in training sessions, moving from Kermanshah, disease and new symptoms during the study.

Intervention groups
Aerobic group training (1 hour) includes the use of Treadmills, Stationary bikes, Ergometer, warm-up and cool-down. Combined group exercises (1 hour) include: use of Treadmill, Stationary cycling, Ergometer cycle and Resistance training During the sessions, it will increase from 8 repetitions of three sets to 15 repetitions. Warm-up and cool-down. Control group patients do not undergo training. In the patients of all three groups, before and after the trial, Structural and Functional indices of the Heart, Hemodynamic and Hemorheological factors are examined.

Main outcome variables
Structural and Functional indices of the Heart, Hemodynamic and Hemorheological variables

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221031056349N1**
Registration date: **2023-03-18, 1401/12/27**
Registration timing: **prospective**

Last update: **2023-03-18, 1401/12/27**
Update count: **0**

Registration date
2023-03-18, 1401/12/27

Registrant information

Name
Peyman Kaikhosro Doulatyari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 83 3836 0295

Email address
p.k.doulatyari@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Eight Weeks Aerobic and Combined Exercise on Hemodynamic, Hemorheological, Structural and Functional indicators of the Heart in Middle-Aged Male Patients Undergoing Coronary Artery Bypass Graft

Public title

The Effect of Eight Weeks of Aerobic and Combined Exercises in Middle-Aged Male Patients Undergoing Coronary Artery Bypass Graft Surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Men Have undergone Coronary Artery Surgery within the previous 8 Weeks The Heart's contractile strength should be above 40% Take the same Heart medication Surgery should be done by the same Surgeon and Echo by the same Cardiologist No smoking for at least three months

Exclusion criteria:

Musculoskeletal disease that hinders the Patient's activity Smoking Exercise activity in addition to the current study program Moved from Kermanshah Illness, Surgery or severe limiting pain Taking sports supplements or special drugs

Age

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

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The way to select the subjects is that people who are interested in participating in the trial are first invited. Then, the selection of the subjects is done in such a way that among the subjects, a researcher-made questionnaire containing information related to Name, Age, Height, Weight, History of sports activities, use of Sports supplements, Smoking, History of diseases and type of Drugs is prepared. And it is provided to the subjects for completion. After examining the answers of the subjects to the questions in the questionnaire, people who have a history of regular sports activity, participation in a weight training program, use of sports supplements, a history of pain, discomfort and surgery in the organs and musculoskeletal system, a history of smoking and limiting diseases If they do not have and meet the conditions to participate in the research, they will participate in the trial. At first, the subjects are visited and evaluated by a specialist doctor to ensure that they are not prohibited from participating in exercise groups. Then, 30 subjects between the ages of 45 and 65 are selected from among the qualified candidates. Each subject is assigned a number and randomly placed in a special group.

Blinding (investigator's opinion)

Single blinded

Blinding description

At first, it is explained to all the subjects that they are participating in a study, and after the explanation, a consent form is obtained. But the subjects do not know which study group they are in.

Placebo

Not used

Assignment

Factorial

Other design features

In this study, Structural and Functional indicators of the Heart and Hemodynamic and Hemorheological variables are investigated simultaneously.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Islamic Azad University- Kermanshah Branch

Street address

End of Farhikhtegan Blvd, Ferdowsi Square

City

Kermanshah

Province

Kermanshah

Postal code

6718997551

Approval date

2023-03-07, 1401/12/16

Ethics committee reference number

IR.IAU.KSH.REC.1401.002

Health conditions studied

1

Description of health condition studied

Coronary artery occlusion

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
The size and amount ofStructural indicators of the Heart
Timepoint
Before starting the study and 8 weeks later
Method of measurement
Echocardiography device

2

Description
The level of functional indicators of the Heart
Timepoint
Before starting the study and 8 weeks later
Method of measurement
Echocardiography device

3

Description
The percentage of people with high Hemodynamic indices
Timepoint
Before starting the study and 8 weeks later
Method of measurement
Sphygmomanometer

4

Description
The percentage of people with high Hemorheological indices
Timepoint
Before starting the study and 8 weeks later
Method of measurement
laboratory equipment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First intervention group, Aerobic exercises.Three sessions per week for 8 weeks and each session is one hour. Before and after the trial, Echocardiography (Structural and Functional indices of the Heart), Hemodynamic and Hemorheological factors are checked.
Category
Rehabilitation

2

Description
Intervention group: The Second intervention group, Combined exercises group.Three sessions per week for 8 weeks and each session is one hour.Before and after the trial, Echocardiography (Structural and Functional indices of the Heart), Hemodynamic and Hemorheological factors are checked.
Category
Rehabilitation

3

Description
Control group: In this group, subjects do not exercise. Before and after the trial, Echocardiography (Structural and Functional indices of the Heart), Hemodynamic and Hemorheological factors are checked.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali(A) Cardio Vascular Research, Education and Treatment Center
Full name of responsible person
Sedigheh Hosseinpour Delavar
Street address
Shahid Beheshti Blvd
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Email
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Web page address
https://imamali.kums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Arash Buchani
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End of Farhikhtegan Blvd, Ferdowsi Square
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Kermanshah
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Email

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Web page address

https://kermanshah.iau.ir/

Grant name

-

Grant code / Reference number

-

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

No

Title of funding source

Islamic Azad University of Kermanshah

Proportion provided by this source

10

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

Kermanshah University of Medical Sciences

Full name of responsible person

Peyman Kaikhosro Doulatyari

Position

PHD student

Latest degree

Master

Other areas of specialty/work

Exercise physiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Peyman Kaikhosro Doulatyari

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)

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

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

Title and more details about the data/document

Means and standard deviations of descriptive data and pre- and post-trial data can be shared after de-identifying subjects.

When the data will become available and for how long

After the publication of the article

To whom data/document is available

Researchers of scientific and academic institutions

Under which criteria data/document could be used

No new analysis is allowed. Researchers can refer to the results

From where data/document is obtainable

To access the general results, please send an email to p.k.doulatyari@gmail.com

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

After the request to the e-mail, it will be answered within a week at most

Comments