

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effect of a period of combined training on Leptin, Adiponectin and Resistin in Middle-aged men after Coronary artery bypass surgery (CABG)

Protocol summary

Study aim

Effect of a period of combined training on Leptin, Adiponectin, and Resistin in Middle-aged men after Coronary artery bypass surgery (CABG)

Design

The sample will be picked among the population and with respect to entry condition to test voluntarily and based on availability. 26 men who undergone bypass surgeries in the 40-60 age range and by available sampling method will be selected, and randomly they were categorized into 12 and 14 individuals experimental and control.

Settings and conduct

Cardiac Rehabilitation Center of Javad Al-A'meh
Cardiovascular Hospital, Mashhad

Participants/Inclusion and exclusion criteria

-In the 40-60 age range -Being interested to participate in research -Hearing, cognitive and visual health -systolic blood pressure higher than 160 mmHg and diastolic blood pressure -higher than 100 mmHg - Lack of suffering from acute and specific diseases that prevent doing exercises -The subjects who were taking the same medications -Not use of neurological medications -Not use of aid equipment to walk e.g by cane and walker -the occurrence of ventricular arrhythmias -to be observed Myocardial Infarction in the ECG during training sessions -respiratory disorders during rehabilitation and training -unstable angina

Intervention groups

Combined aerobic and resistance training

Main outcome variables

Independent variables: eight-week aerobic and resistance exercise rehabilitation program. Related variables: Independent variable: Combined rehabilitation exercises, dependent variable: Leptin, adiponectin, and resistin factors.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201031049202N1**

Registration date: **2020-11-13, 1399/08/23**

Registration timing: **retrospective**

Last update: **2020-11-13, 1399/08/23**

Update count: **0**

Registration date

2020-11-13, 1399/08/23

Registrant information

Name

Hossein Nikkar

Name of organization / entity

Islamic azad University, Neyshabour branch

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-04, 1399/07/13

Expected recruitment end date

2020-10-11, 1399/07/20

Actual recruitment start date

2020-10-11, 1399/07/20

Actual recruitment end date

2020-11-03, 1399/08/13

Trial completion date

2020-11-03, 1399/08/13

Scientific title

Effect of a period of combined training on Leptin, Adiponectin and Resistin in Middle-aged men after Coronary artery bypass surgery (CABG)

Public title

Effect of a period of combined training on Leptin, Adiponectin, and Resistin in Middle-aged men after Coronary artery bypass surgery (CABG)

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

In the 40-60 age range Being interested to participate in research Hearing, cognitive and visual health systolic blood pressure higher than 160 mmHg and diastolic blood pressure higher than 100 mmHg Lack of suffering from acute and specific diseases that prevent doing exercises The subjects who were taking the same medications Not use of neurological medications Not use of aid equipment to walk e.g by cane and walker

Exclusion criteria:

Cardiac arrhythmia o be observed Myocardial Infarction in the ECG during training sessions respiratory disorders during rehabilitation and training unstable angina

Age

From **40 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **26**

Actual sample size reached: **26**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

thics committee of Islamic Azad University, Neyshabur Branch

Street address

Research Blvd., Islamic Azad University , Neyshabour

Branch, Neyshabour, Khorasan Province, Iran

City

Neyshabur

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Razavi Khorasan

Postal code

9319975853

Approval date

2020-09-24, 1399/07/03

Ethics committee reference number

IR.IAU.NEYSHABUR.REC.1399.012

Health conditions studied

1

Description of health condition studied

Coronary artery bypass graft patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of people who underwent coronary artery bypass grafting

Timepoint

before cardiac rehabilitation period and end of it.

Method of measurement

Patients ECG, condition of physical fitness, Cardiovascular and Ejection Fraction (EF) risk factors, the Rehabilitation program results

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Rehabilitation program (aerobic, resistance training),26 men who undergone bypass surgeries in the 40-60 age range, and by available sampling method will be selected, and randomly they were categorized into two groups.14 individuals experimental group. Participants as an experimental group in the rehabilitation center of Javadalameh Heart Hospital completed exercises and In order to reduce the mediator and mixer effect in research, according to aspects of control the short-term effects of the diet based on the desired indicators, in this session, the doctor recommended eating ready meals at least 24 hours before exercise program and blood sampling. they avoided caffeinating beverages and similar diets. Thus, 14 people (combined exercise group) be selected. Examples in the same environment and conditions have performed combined sports activities.

Category

Lifestyle

2

Description

Control group: (Patients without rehabilitation program):26 men who undergone bypass surgeries in the 40-60 age range, and by available sampling method will be selected, and randomly they were categorized into two groups.12 individuals control group, the control group included those who person that didn't participate in the cardiac rehabilitation program after surgery and haven't any regular physical activity and In order to reduce the mediator and mixer effect in research, according to aspects of control the short-term effects of the diet based on the desired indicators, in this session, the doctor recommended eating ready meals at least 24 hours before exercise program and blood sampling. they avoided caffeinating beverages and similar diets. Thus,12 people (control group) be selected. Examples in the same environment and conditions have performed combined sports activities.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation Center of Javad Allameh Hospital

Full name of responsible person

Dr. Emad Alavinia

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Honarestan Blvd, Mashhad, Khorasan Province, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Allameh Hospital

Full name of responsible person

Dr. Emad Alavinia

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Web page address

http://javadalaemehosp.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Allameh Hospital

Proportion provided by this source

50

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Ferdowsi University of Mashhad

Full name of responsible person

Dr. Amir Rashidlamir

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise physiology, metabolism and biochemistry

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Contact

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Exercise physiology, biochemical and metabolism

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

some sections of results about some information on the main outcome can be shared.

When the data will become available and for how long

the access time is period from 1399 onwards

To whom data/document is available

Only supervisors and advisors

Under which criteria data/document could be used

for use, it must be coordinated with supervisors, consultants, and researchers

From where data/document is obtainable

Hossein Nikkar h.nikkar@iau-neyshabur.ac.ir

09151601391 Dr. Amir Rashidlamir

amir.rashidlamir@gmail.com 09151514174

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

First, the request should be given to the supervisors and advisors. After their approval, the data will be assigned.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University, Neyshabur Branch

Full name of responsible person

Dr Rambod Khajei

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

Exercise Physiology

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