Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

Phone

+98 56 3243 0381

Email address

h.nikkar@iau-neyshabur.ac.ir

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

Province
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
Street address
Honarestan Blvd, Mashhad, Khorasan Province, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9178613111
Phone
+98 51 3881 6010
Email
info@jhosp.org
Web page address
http://javadalaemehosp.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Allameh Hospital
Full name of responsible person
Dr. Emad Alavinia
Street address
Honarestan Blvd, Mashhad, Khorasan Province,Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9178613111
Phone
+98 51 3881 6010
Email
info@jhosp.org
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
Street address
Azadi Square, Ferdowsi University, Mashhad,Razavi khorasan province, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948974
Phone
+98 51 3880 5000
Email
amir.rashidlamir@gmail.com
Web page address
https://www.um.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ferdowsi University of Mashhad
Full name of responsible person
Amir Rashid Lamir
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Exercise physiology, biochemical and metabolism
Street address
Azadi Square, Ferdowsi University, Razavi khorasan province, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948974
Phone
+98 51 3880 5000
Email
amir.rashidlamir@gmail.com
Web page address
https://www.um.ac.ir/

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
Ph.D.
Other areas of specialty/work
Exercise Physiology
Street address
Research Blvd., Islamic Azad University, Neyshabour, Khorasan Razavi Province, Iran
City
Neyshabur
Province
Razavi Khorasan
Postal code
9319975853
Phone
+98 51 4262 1901
Email
r.khajeie@gmail.com
Web page address
https://iau-neyshabur.ac.ir/

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