Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of a combined training session on ABCA5 and ApoB gene expression and white blood cell lipid profile in middle-aged men after cardiac bypass surgery

Protocol summary

Study aim
The effect of eight weeks of resistance training on the expression of ABCG5 gene, APOB plasma levels And middle-aged men 's lipid profile after coronary artery bypass grafting

Design
The present research design will be quasi-experimental and laboratory research. The statistical population of the present study is 60 middle-aged male patients who underwent coronary artery bypass grafting at least 2 and at most 4 months ago and will be referred to Javad Al-A'meh Heart Hospital in Mashhad. The statistical sample will be selected voluntarily from the statistical population according to the conditions of entering the research. Among them, 30 men who underwent bypass surgery, with an age range of 65-50 years and by available sampling method were selected and divided into two experimental groups (15 people) and control group (15 people). be. These exercises will be performed in rehabilitation phase 3 and patients will perform exercise exercises in this phase for the first time.

Settings and conduct
The quasi-experimental study will be completed with a pre-test-post-test design in three intervention groups in Javad Al-A'meh Hospital under the supervision of a physician for eight weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria (Cognitive health, visual and auditory, no blood pressure higher than 160 mm Hg and diastolic higher than 100 mm Hg. Do not use the same drugs, do not use assistive devices such as walkers and age range 50 to 65 years who underwent coronary artery bypass grafting Criteria for non-admission were lack of permission from a cardiologist and lack of inclusion criteria

Intervention groups
The intervention in the present study will be eight weeks of endurance and resistance training.

Main outcome variables
ABCA5 gene expression - B lipoprotein - Lipid profile - Functional factors

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210426051087N1**
Registration date: **2021-06-11, 1400/03/21**
Registration timing: **retrospective**

Last update: **2021-06-11, 1400/03/21**
Update count: **0**

Registration date
2021-06-11, 1400/03/21

Registrant information

Name
mahbobeh sazgar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3880 3000

Email address
mahboobehsazegar@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-20, 1399/02/01

Expected recruitment end date
2020-04-21, 1399/02/02

Actual recruitment start date

2020-05-22, 1399/03/02

Actual recruitment end date

2020-08-24, 1399/06/03

Trial completion date

2020-08-26, 1399/06/05

Scientific title

The effect of a combined training session on ABCA5 and ApoB gene expression and white blood cell lipid profile in middle-aged men after cardiac bypass surgery

Public title

The effect of combined rehabilitation exercises in patients with coronary artery bypass grafting

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 50-60 years Willingness to participate in research Cognitive, visual and auditory health No systolic blood pressure higher than 160 mmHg and diastolic blood pressure higher than 100 mmHg No acute and advanced diseases that prevent the exercises considered in this study.

Exclusion criteria:

Existence of symptoms and heart failure Taking over-the-counter medications Inability to perform sports activities

Age

From **50 years** old to **60 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be determined by random blocking method with 4 blocks using the table of random numbers of Software Allocation Random software. Blocking and allocation sequencing for concealment will be done by the person not involved in the research.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In fact, this study was performed to investigate the effect of endurance and resistance training on the physiological status of patients with coronary artery bypass grafting.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Neyshabour Branch

Street address

RESEARCH Ave, Islamic Azad University Complex Neyshabur Branch

City

neyshabur

Province

Razavi Khorasan

Postal code

9319797139

Approval date

2020-09-24, 1399/07/03

Ethics committee reference number

IR.IAU.NEYSHABUR.REC.1400.001

Health conditions studied

1

Description of health condition studied

Chronic ischaemic heart disease, unspecified

ICD-10 code

I25.7

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris

Primary outcomes

1

Description

ABCG5 gene expression

Timepoint

24 hours before the start of the protocol and 48 hours after the end of the last training protocol session

Method of measurement

REAL TIME-PCR method

2

Description

APOB plasma levels

Timepoint

24 hours before the start of the protocol and 48 hours after the end of the last training protocol session

Method of measurement

ELISA laboratory method

3

Description

LDL plasma levels

Timepoint

24 hours before the start of the protocol and 48 hours after the end of the last training protocol session

Method of measurement

ELISA laboratory method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Aerobic-resistance training group. After taking blood samples and functional tests (5-second unassisted sit-up test (TUG), 3-meter back and forth (BBS) and cardiorespiratory function (6-minute walk)), participants are asked Start the training session with an aerobic program in three parts: walking on a treadmill (20 to 30 minutes), cycling (10 to 12 minutes) and manual ergometer (10 minutes) with an intensity of 60% of maximum heart rate. Then, by performing a resistance training program in three consecutive sets with 8 to 15 repetitions, the training session ends. The intensity of resistance training can be changed by using different colors (yellow to pink) of Traband. Then, at the end of the training period, blood is taken again and the functional test is measured again.

Category

Prevention

2

Description

Intervention group: Resistance-aerobic training group. After taking blood samples and functional tests (5-second unassisted sit-up test (TUG), 3-meter back and forth (BBS) and cardiorespiratory function (6-minute walk)) from participants Is asked to Perform resistance training program in three consecutive sets with 8 to 15 repetitions. The intensity of resistance training can be changed by using different colors (yellow to pink) of Traband. Then the training session is completed with an aerobic program in three parts that included walking on a treadmill (20 to 30 minutes), pedaling on a bicycle (10 to 12 minutes) and hand ergometer (10 minutes) with an intensity of 60% of maximum heart rate. Also, at the end of the training period, blood is taken again and the functional test is measured again.

Category

Prevention

3

Description

Control group: did not have any sports activities and supplementation and illegal drugs during the research protocol

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Javadalameh Specialized Heart Hospital, Mashhad

Full name of responsible person

Dr. Amir Rashid Lamir

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Amir Rashid Lamir
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
We apologize for publishing the data because of the ethical commitment it has made to patients and the Patient Rehabilitation Center.
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
Yes - There is a plan to make this available
Title and more details about the data/document
The data file will be provided as a spss file
When the data will become available and for how long
From 1400 to 1402
To whom data/document is available
Researchers and researchers and academic and scientific institutions
Under which criteria data/document could be used
There is data usage and analysis for researchers
From where data/document is obtainable
To use the data, refer to the email m_akbari64@hotmail.com

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

Email the person in charge of correspondence

Comments

Except for ethical criteria, the rest of the data will be made available to researchers