

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of a combined training course on lipid profile; APOA levels and expression of ABCB4 white blood cell gene in middle-aged men after cardiovascular bypass surgery

Protocol summary

Study aim

The effect of a combined training session on lipid profile; APOA levels and ABCB4 gene expression of white blood cells in middle-aged men after cardiovascular bypass surgery

Design

The statistical sample of this study consisted of 30 middle-aged men who had previously undergone coronary artery bypass grafting. This is a quasi-experimental study that was randomly divided into two groups of control (n = 15, endurance and resistance combined training (n = 15) by selective sampling.

Settings and conduct

All stages of the study will be performed in compliance with the rules of research ethics and under the supervision of the ethics committee of Javadlameh Cardiovascular Hospital in Mashhad. After the initial blood sampling, samples will be pre-tested and at the end of 24 sessions post-test will be performed. Walking on a treadmill for 20 to 30 minutes, pedaling on a stationary bike for 10 to 12 minutes, using a manual ergometer for 10 minutes, and resistance training include: three repetitive sets; three movements for the upper limbs and two movements for the lower limbs.

Participants/Inclusion and exclusion criteria

1. Have previously undergone coronary artery bypass graft surgery. 2. Have a relative readiness to perform exercises. 3. Between at least 2 months and at most 4 months have passed since the coronary artery surgery of their heart.

Intervention groups

The experimental group performed combined exercises for eight weeks, including resistance and aerobic exercises, but the control group had no activity.

Main outcome variables

ABCB4 gene expression ; APOA levels ; Lipid profile;

General information

Reason for update

Acronym

CABG

IRCT registration information

IRCT registration number: **IRCT20201117049424N1**

Registration date: **2021-06-09, 1400/03/19**

Registration timing: **retrospective**

Last update: **2021-06-09, 1400/03/19**

Update count: **0**

Registration date

2021-06-09, 1400/03/19

Registrant information

Name

Robabe Mahmoodi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-24, 1396/06/02

Expected recruitment end date

2018-05-23, 1397/03/02

Actual recruitment start date

2018-05-23, 1397/03/02

Actual recruitment end date

2018-10-07, 1397/07/15

Trial completion date

2018-10-07, 1397/07/15

Scientific title

The effect of a combined training course on lipid profile; APOA levels and expression of ABCB4 white blood cell gene in middle-aged men after cardiovascular bypass surgery

Public title

We perform combined exercises that include aerobic and resistance training on subjects who are middle-aged men who have undergone cardiac bypass surgery. We examined its effects on ABCB4 gene expression, APOA levels and reverse cholesterol transfer.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Systolic blood pressure greater than 160 mmHg and diastolic blood pressure higher than 100 mmHg. Cognitive, visual and auditory health Use walking aids such as canes and walkers. eir operating capacity should not be less than five meters. Hermet expresses consumption of 3.5 ml of oxygen per kilogram of body weight per minute, which was estimated based on the modified Bruce test (Fallahi Vagini 2012). Use of neuroleptics. Age range 50 to 60 years At least two months have passed since their operation

Exclusion criteria:

Unstable angina Uncompensated heart failure Myocardial infarction over the past four weeks Ventricular arrhythmia

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: **30**

More than 1 sample in each individual

Number of samples in each individual: **15**

Actual sample size reached: **30**

More than 1 sample in each individual

Actual sample size in each individual: **15**

There will be 15 participants in the control group and 15 participants in the experimental group

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This project is part of a doctoral thesis that will be performed on patients with coronary artery bypass

grafting and will examine the effect of rehabilitation exercises on patients with coronary artery bypass grafting.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University of Neyshabour

Street address

Neishabour Islamic Azad University

City

Neyshabour

Province

Razavi Khorasan

Postal code

9319975853

Approval date

2017-04-23, 1396/02/03

Ethics committee reference number

IR.IAU.NEYSHABUR.REC.1399.026

Health conditions studied

1

Description of health condition studied

Cardiovascular disease

ICD-10 code

ICD-10 code description

I60-I69 بیماریهای قلبی و عروقی

2

Description of health condition studied

Coronary artery disease I70-I79

ICD-10 code

ICD-10 code description

I70-I79 بیماریشریان کرونری

3

Description of health condition studied

Circulatory system disease I95-I99

ICD-10 code

ICD-10 code description

I95-I99 اختلالات نامشخص سیستم گردش خون

Primary outcomes

1

Description

ABCB4 gene expression

Timepoint

24 hours before the start of the protocol and 48 hours

after the last training session
Method of measurement
ABCB4 gene expression and ELISA method

2

Description
APOA plasma levels,
Timepoint
24 hours before the start of the protocol
Method of measurement
Gene expression and ELISA method

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group": 8 weeks of cardiac rehabilitation (aerobic training and resistance training) including 3 sessions per week with an intensity of 50-80% of the reserve heart rate or Burg criterion the 13-11 depending on the strength of the tests and for each session up to 90 minutes as follows: "Intervention group 1:; 2, Walking on a treadmill for 20 to 30 minutes ";;" Intervention group: 1:; 3, pedaling on a stationary bike 12-10 minutes ";; Intervention group: 1:; 4, using manual ergometer is 10 minutes and resistance training includes;" Intervention group 1:5; There are three movements for the upper limb and two movements for the lower limb.
Category
Prevention

2

Description
Control group: Control group: No exercise was given to the control group.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Javadalameh Cardiovascular Hospital, Mashhad
Full name of responsible person
Dr Emad Alaviniya
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Dr. Rambod Khajeh
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Neishabour Azad University
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Neishabour 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
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Position

Associate Professor

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

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

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable