Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of combined training on ABCG4 gene expression and interleukin 4 and interleukin 10 factors in middle-aged men's blood mononuclear cells after coronary artery bypass graft

Protocol summary

Study aim

The purpose of the present study; Evaluation of the effect of combined training on ABCG4 gene expression and the level of interleukin-4 and interleukin-4 factors in blood mono nuclear cells in middle-aged men after vascular bypass surgery (CABG)

Design

The present research design will be quasi-experimental and laboratory research and will be applied . The statistical population of the present study will consist of 60 middle-aged male patients who have previously undergone coronary artery bypass graft surgery and will be referred to Javad Al-A'meh Heart Hospital in Mashhad. They will be elected. Also about the number of subjects due to the difficulty of the test used in the study and the need to select patients who have undergone coronary artery bypass graft surgery to perform the test, and also using the Cochran's formula to determine the sample size with 95% confidence, the number 20 n =, was obtained.

Settings and conduct

All stages of the research will be carried out by observing the rules of research ethics and under the supervision of the ethics committee of Javad Al-Aimeh Cardiovascular Hospital in Mashhad and under the supervision of a cardiologist. After the initial blood sampling, the samples will be per-tested and at the end of 24 post-test sessions.

Participants/Inclusion and exclusion criteria

1. People who have previously undergone coronary artery bypass grafting 2. In terms of physical strength, be relatively ready to do exercises 3. 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

The effect of a combined training course on reverse cholesterol transfer factors and reduction of inflammatory factors

General information

Reason for update

Acronym

CABG

IRCT registration information

IRCT registration number: **IRCT20201115049393N1**
Registration date: **2021-01-30, 1399/11/11**
Registration timing: **retrospective**

Last update: **2021-01-30, 1399/11/11**
Update count: **0**

Registration date

2021-01-30, 1399/11/11

Registrant information

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Fahimeh Yonesi

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

2018-03-22, 1397/01/02

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 combined training on ABCG4 gene expression and interleukin 4 and interleukin 10 factors in middle-aged men's blood mononuclear cells after coronary artery bypass graft

Public title
The effect of combined training on ABCG4 gene expression and interleukin 4 and interleukin 10 factors in middle-aged men's blood mononuclear cells after coronary artery bypass graft
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1. No systolic blood pressure higher than 160 mm Hg and diastolic blood pressure higher than 100 mm Hg 2. Cognitive, visual and auditory health 3. Do not use neuroleptics 4. Do not use walking aids such as canes and walkers 5. At least 2 months have passed since their operation 6. Their functional capacity should not be less than five met. Each met represents a consumption of 3.5 ml of oxygen per kilogram of body weight per minute, which was estimated based on a modified Bruce test 7. Age range 50 to 65 years
Exclusion criteria:
Unstable angina, irreversible heart failure, myocardial infarction over the past four weeks, ventricular arrhythmias.
Age
From **50 years** old to **65 years** old
Gender
Male

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **26**
Actual sample size reached: **26**
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 has been performed on patients with coronary artery bypass grafting and examines the effect of combined rehabilitation exercises on patients with coronary artery bypass grafting.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Committee of Ethics in Biomedical Research, Islamic Azad University. neyshabour unit
Street address
Research Blvd., Islamic Azad University Complex, Neyshabur Branch Khorasan Razavi Province, Neyshabur
City
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Province
Razavi Khorasan
Postal code
9319975853
Approval date
2017-04-23, 1396/02/03
Ethics committee reference number
IR.IAU.NEYSHABUR.REC.1399.016

Health conditions studied

1

Description of health condition studied
Patients with coronary artery bypass grafting
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
ABCG4 gene expression and plasma levels of interleukin 4 and interleukin 10
Timepoint
24 hours before the start of the protocol and 48 hours after the last training session
Method of measurement
Real-time-PCT gene expression and ELISA method

Secondary outcomes

1

Description
ABCG4 gene expression of interleukin 4 and interleukin 10
Timepoint
24 hours before and 24 hours after the first and last training session

Method of measurement
Real-time-PCR method and ELISA method

Intervention groups

1

Description
Control group: Intervention group: 8 weeks of cardiac rehabilitation (aerobic training and resistance training) including 3 sessions per week with an intensity of 80-50% of the reserve heart rate or Borg standard 11-11 depending on the ability of the subjects and for each session up to 90 minutes The following: Walking on a treadmill for 20 to 30 minutes, cycling on a stationary bike for 10 to 12 minutes, using a manual ergo meter for 10 minutes, and resistance training include three repetitive sets, three movements for the upper limbs, and two lower limbs. The training course along with the usual treatment of risk factors for heart disease will include hyperglycemia and inflammation. Exercises will be performed in accordance with the principle of overload.
Category
Rehabilitation

2

Description
Control group: During this period, this group did not have any sports activities
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Javadalameh Specialized Heart Hospital, Mashhad
Full name of responsible person
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Sponsors / Funding sources

1

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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
Research Branch of neyshabour 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
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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
Not applicable

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