Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of eight weeks of combined training on the serum macrophages phenotype of cardiac patients after coronary coronary artery bypass graft surgery

Protocol summary

Study aim

The aim of the present study is to investigate the effect of eight weeks of combined training on serum macrophages phenotype after coronary arteries bypass graft surgery.

Design

Clinical trial with control group, Parallel groups, Not blinded, Not randomized

Settings and conduct

Study population of patients with coronary artery bypass graft surgery which has positive exercise test and are not present in the cardiac rehabilitation of Afshar Hospital in Yazd. Patients are not willing to take part in the study or create any cardiovascular disease or skeletal problem during the study will be dropped out. Individuals in non-randomly divided into two groups, including a group that will receive cardiac rehabilitation and drug treatment, and the control group that will only receive pharmaceutical treatment. In each group, 10 people will be examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Coronary artery bypass graft surgery, low risk and Ejection fraction of 30%. Exclusion criteria: unstable angina, uncorrected heart failure, cardiac infarction over the past four weeks, ventricular arrhythmias.

Intervention groups

Intervention group:8 weeks cardiac rehabilitation (aerobic exercises and resistance training) included 3 sessions per week with an intensity of 50-80% of the heart rate reserve or the criterion of Borg 11-13 depending on the ability of the subjects and the resistance training consists of three repetitive sets, three movements for upper limbs and two lower extremity movements. Training course with the usual treatment of cardiac risk factors will include high hyperlipidemia and hypertension. Control group: Those who do not participate in the rehab program despite their doctor's recommendation and the usual treatment.

Main outcome variables

Classical Macrophage ,Alternative Macrophage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190529043755N1**
Registration date: **2019-07-01, 1398/04/10**
Registration timing: **retrospective**

Last update: **2019-07-01, 1398/04/10**
Update count: **0**

Registration date

2019-07-01, 1398/04/10

Registrant information

Name

Mohammad Marandi

Name of organization / entity

University of Esfahan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-12, 1396/07/20

Expected recruitment end date

2018-04-09, 1397/01/20

Actual recruitment start date
2018-01-10, 1396/10/20
Actual recruitment end date
2018-11-14, 1397/08/23
Trial completion date
2018-11-14, 1397/08/23

Scientific title
The effect of eight weeks of combined training on the serum macrophages phenotype of cardiac patients after coronary coronary artery bypass graft surgery

Public title
Combined training on the serum macrophages phenotype of cardiac patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients after Coronary Artery Bypass Graft Surgery Surgical Injection site restoration, Having a low risk and Ejection fraction of 30%
Exclusion criteria:
Unstable angina Cardiac insufficiency not compensated Myocardial infarction over the past four weeks, Ventricular arrhythmia
Age
No age limit
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Actual sample size reached: **20**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Shahid Sadoughi University of Medical Sciences of Yazd
Street address
Central Organization of Medical Sciences and Health Services,Martyr Dr. Bahonar Square
City
Yazd
Province
Yazd
Postal code
8916978477
Approval date
2017-09-24, 1396/07/02
Ethics committee reference number
IR.SSU.REC.1396.108

Health conditions studied

1

Description of health condition studied
Patients after Coronary Artery Bypass Graft Surgery
ICD-10 code
I25.1
ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
Classical Macrophage Serum Level
Timepoint
24 hours prior to baseline and 24 hours after the intervention period
Method of measurement
Elisa Kit

2

Description
Alternative Macrophage Serum Level
Timepoint
24 hours prior to baseline and 24 hours after the intervention period
Method of measurement
Elisa Kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention Group: 8 weeks cardiac rehabilitation (aerobic exercises and resistance training) included 3 sessions per week with an intensity of 50-80% of the heart rate reserve or the criterion of Borg 11-13 depending on the ability of the subjects and for each session up to 90 minutes as follows:Walking on the treadmill 20 to 30 minutes, the pedal on the fixed bike

10 to 12 minutes, the use of a handheld meter is 10 minutes and the resistance training consists of three repetitive sets, three movements for upper limbs and two lower extremity movements. Training course with the usual treatment of cardiac risk factors will include high hyperlipidemia and hypertension. The exercises will be carried out by observing the principle of overload.

Category

Rehabilitation

2

Description

Control group: Those who do not participate in the rehab program despite their doctor's recommendation and will have the usual treatment of heart disease risk factors include hyperlipidemia and hypertension.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Afshar Heart Rehabilitation Center

Full name of responsible person

Mohammad Reza Vafaei Nasab

Street address

Afshar Hospital in Yazd, Islamic Republic Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Esfahan

Full name of responsible person

Masoud Roknizadeh

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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

University of Esfahan

Proportion provided by this source

100

Public or private sector

Public

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

University of Isfahan

Full name of responsible person

Mohammad Marandi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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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
Due to the confidentiality of some patients' information and their dissatisfaction with the publication
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