Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effects of acute and chronic aerobic exercise training on vascular and systemic inflammatory biomarkers in patients with coronary artery disease after revascularization interventions

Protocol summary

Summary

The aim of this study is to evaluate effects of acute and chronic exercise on vascular and systemic inflammatory biomarkers in patients with coronary artery disease after revascularization interventions (percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG).It was hypothesized that C-reactive protein (CRP) is a biomarker of systemic and vascular adhesion molecules-1(VCAM-1) and pentraxin -3(PTX3) are markers of vascular inflammation. This is a clinical trial study. 70 male patients refers to Shahid Beheshti Hospital of Kashan University of Medical Science with history of coronary artery disease from 11/1/2017 will enroll in our study and will randomly assigned to in intervention group(IG) and control group(CG). IG will participate in one session submaximal aerobic exercise training and then 8 weeks of cardiac rehabilitation program and CG will have a normal daily activities. Before the beginning study, patients will perform a symptom limited exercise test based on Bruce protocol and their maximal heart rate and vo2 peak will be measured. Exercise intensity will be set between 65 to 75 percent of maximal heart rate. One day before the study start, patients will familiar with cardiac rehabilitation instrument and perform exercise test. After 24 hours patients will prepare to participate in acute submaximal aerobic exercise session include 15minutes warm up, 35 minute submaximal aerobic exercise on treadmill and ergometer and 10 minutes cool down. Patients in IG performed 8 weeks cardiac rehabilitation program(CRP) at 70 % of maximum heart rate,3-4 times a week each session 60 min consist of 15 min warm-up, 30 min submaximal aerobic exercise on tread mill and ergo meter and at the end 10 min cool down, Blood blood samples will obtain from the antecubital vein at baseline, 30 min after the of aerobic submaximal session and after 8 weeks cardiac rehabilitation program to measure plasma levels of pentraxin 3(PTX3), vascular cell adhesion molecule 1 (VCAM-1), C-reactive protein (CRP) and lipid profile.The blood collect in chilled tube with EDTA and then centrifuge at 2000 *g for 15 min at 4 C then plasma will store at -20 c refrigerator. Inflammatory biomarkers will determine by means of enzyme-linked immunosurbent assay kits.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610085136N3**
Registration date: **2017-05-04, 1396/02/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-05-04, 1396/02/14

Registrant information

Name

Fatemeh Basati

Name of organization / entity

Mohaghagh Ardebili University

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Recruitment status

Recruitment complete

Funding source

Mohaghegh Ardebili University, Kashan University of Medical Sciences

Expected recruitment start date
2016-10-22, 1395/08/01
Expected recruitment end date
2017-04-20, 1396/01/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of acute and chronic aerobic exercise training on vascular and systemic inflammatory biomarkers in patients with coronary artery disease after revascularization interventions

Public title
Effects of cardiac rehabilitation on inflammation
Purpose
Prevention
Inclusion/Exclusion criteria
Exclusion criteria: Patients were excluded if they have congestive failure; immnomodulatory or anti-inflammatory medications other than Aspirin; or known history of immune related disorders; unstable angina; resting systolic blood pressure >200 mmhg or diastolic blood pressure>10mmhg; uncontrolled bradycardia or tachycardia. Inclusion criteria:history of CABG and PCI; have ability to present in cardiac rehabilitation program; not having any physical exercise out of cardiac rehabilitation program; cardiac rehabilitation start 2 month after CABG and 1 month after PCI
Age
From **35 years** old to **65 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
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
Kashan University of Medical Sciences Ethic Committee
Street address
,Kashan University of Medical Sciences, Medicine faculty
City
Kashan
Postal code
Approval date
2016-10-01, 1395/07/10
Ethics committee reference number
IR.KAUMS.REC1395.48

Health conditions studied

1

Description of health condition studied
Diseases of the circulatory system
ICD-10 code
I20-I25
ICD-10 code description
Ischaemic heart diseases

Primary outcomes

1

Description
PTX3
Timepoint
before and 30 min after one session submaximal aerobic exercise, and after 8 weeks cardiac rehabilitation program
Method of measurement
Human Pentraxin 3 Elisa Kit 96t - Zellbio Germany

2

Description
VCAM-1
Timepoint
before and 30 min after one session submaximal aerobic exercise, and after 8 weeks cardiac rehabilitation program
Method of measurement
Human VCAM-1 Elisa Kit 96t - Diaclone France

3

Description
CRP
Timepoint
before and 30 min after one session submaximal aerobic exercise, and after 8 weeks cardiac rehabilitation program
Method of measurement
Pars Azmon kit

Secondary outcomes

1

Description
weight
Timepoint
before and after intervention
Method of measurement
balance scales

2

Description
body mass index
Timepoint
before and after intervention
Method of measurement
weight divided by height square(kg/m2)

3

Description
fasting blood glucose
Timepoint
before and after intervention
Method of measurement
blood analysis

4

Description
blood pressure
Timepoint
before and after intervention
Method of measurement
sphygmomanometer

5

Description
total cholestrol
Timepoint
before and after intervention
Method of measurement
blood analysis

6

Description
HDL- cholestrol
Timepoint
before and after intervention
Method of measurement
blood analysis

7

Description
LDL-cholestrol
Timepoint
before and after intervention
Method of measurement
blood analysis

8

Description
triglyceride
Timepoint
before and after intervention
Method of measurement
blood analysis

Intervention groups

1

Description
Intervention Group: . The cardiac rehabilitation comprise 24 sessions of exercise, schedule over 8 weeks in the Cardiac Rehabilitation Center of SHahid Beheshti Hospital (Kashan, Iran). Each session last 60 minutes and included 10-20 minutes of warm-up followed by 20-40 minutes of aerobic exercise and a 10-minute cool-down. According to the determined risk, the intensity of exercise was calculated as 65-75% of maximum heart rate achieve on the exercise test. The exercise will perform under electrocardiographic monitoring if the patient was at high risk. All patients receive psychological, nutritional, and smoking cessation recommendations.
Category
Rehabilitation

2

Description
Control group: patients in this group will have their ordinary medications, and life style.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Cardiac Rehabilitation Center of Shahid Beheshti Hospital
Full name of responsible person
Street address
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor Of Research Kashan University of Medical Sciences
Full name of responsible person

Dr. Allahyar Golabchi Gilani

Street address

University of Medical Sciences, Medicine Faculty

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor Of Research Kashan University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Vice Chancellor Of Research Mohaghegh Ardebili University

Full name of responsible person

Dr.Marefat Siahkouhian

Street address

Mohaghagh Ardebili University, Daneshgah Blvd,

City

Ardebil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor Of Research Mohaghegh Ardebili University

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty