

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 VO_2 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 15 minutes 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 treadmill and ergometer 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 immunosorbent 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

Mohaghigh Ardebili University

Country

Iran (Islamic Republic of)

Phone

+98 21 2298 9007

Email address

fatemeh.basati1987@gmail.com

Recruitment status

Recruitment complete

Funding source

Mohaghigh 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; immunomodulatory 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

AgeFrom **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 Siahkhouhian
Street address
 Mohaghigh 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
 Mohaghigh Ardebili University
Full name of responsible person
 Fatemeh Basati

Position
 Doctor of Philosophy Student
Other areas of specialty/work
Street address
 Mohaghigh Ardebili University, Daneshgah Blvd,
City
 Ardebil
Postal code
Phone
 +98 21 2298 9007
Fax
Email
 basatifatemeh@yahoo.com;
 fatemeh.basati1987@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
 Mohaghigh Ardebili University
Full name of responsible person
 Fatemeh Basati
Position
 Doctor of Philosophy Student
Other areas of specialty/work
Street address
 Mohaghigh Ardebili University, Daneshgah Blvd,
City
 Ardebil
Postal code
Phone
 +98 21 2298 9007
Fax
Email
 basatifatemeh@yahoo.com ;
 fatemeh.basati1987@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
 Mohaghigh Ardebili University
Full name of responsible person
 Fatemeh Basati
Position
 Doctor of Philosophy Student
Other areas of specialty/work
Street address
 Mohaghigh Ardebili University, Daneshgah Blvd,
City
 Ardebil
Postal code
Phone
 +98 21 2298 9007
Fax
Email
 basatifatemeh@yahoo.com ;
 fatemeh.basati1987@gmail.com
Web page address

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