# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The effects of eight weeks aerobic training and vitamin E & C prescription on plasma levels of MMPS and their tissue inhibitor(TIM1) in patients with CAD

## Protocol summary

**Study aim**

The purpose of this study is to investigate the effects of eight weeks aerobic training and the usage of vitamins E and C on the plasma levels of matrix metalloproteinases (MMPS) 3, 2, 1 and 9 as well as their tissue inhibitor 1 (TIM1)) in patients with coronary artery disease(CAD).

**Design**

This experimental study is conducted on four groups, including three experimental groups with parallel interventions and a control group. 60 subjects are selected non-randomly and available mode and randomly assigned in these four groups.

**Settings and conduct**

This study is carried out in the field of improving the quality of health during the recovery period. supplements in cardiovascular patients. The research design is pre-test, post-test with the implementation of independent variables, which will be implemented in the Cardiac Rehabilitation Center of Bahman Hospital in Zanjan.

**Participants/Inclusion and exclusion criteria**

Patients with coronary artery disease (CAD) who their diagnosis of CAD (with the condition of at least 50% narrowing of at least two main coronary arteries) by cardiologists to be confirmed.

**Intervention groups**

The first group: They will perform aerobic training for eight weeks. The second group: they will take E and C supplements for eight weeks. The third group: Eight weeks of aerobic training will be performed along with taking supplements of vitamins E and C. The control group, during the eight-week experimental period, will only take the drugs prescribed by the physician and will not use any intervention of antioxidant drugs and exercise training

**Main outcome variables**

Investigating the effectiveness of long-term aerobic training on coronary artery remodeling indicators. Investigating the effectiveness of supplementing with antioxidant vitamins on coronary artery remodeling indicators.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20240418061518N1**
Registration date: **2024-05-25, 1403/03/05**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-25, 1403/03/05**
Update count: **0**

**Registration date**

2024-05-25, 1403/03/05

**Registrant information**

**Name**

Mahdi Reza ghlizadeh

**Name of organization / entity**

Islamic Azad university- zanjan branch

**Country**

Iran (Islamic Republic of)

**Phone**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2024-05-21, 1403/03/01

**Expected recruitment end date**

2024-06-20, 1403/03/31

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effects of eight weeks aerobic training and vitamin E & C prescription on plasma levels of MMPS and their tissue inhibitor(TIM1) in patients with CAD

**Public title**
The effect of endurance training and consumption of antioxidant vitamins on disease progression in patients with CVD
**Purpose**
Health service research
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Subjects have coronary artery disease (with the condition of at least 50% narrowing of at least two main coronary arteries), which has been confirmed by cardiologists based on examinations, complete blood tests, echocardiography, exercise stress test and angiography.
**Exclusion criteria:**
using of drugs or other antioxidant supplements other than the supplements considered in this research
**Age**
No age limit
**Gender**
Both

**Phase**
3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Subjects will be selected with non-probability sampling method (Convenience sampling) and will be randomly assigned to four groups based on the functional capacity obtained from the initial exercise stress test.
**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 of islamic azad university. zanjan branvh
**Street address**
Daneshjoo Blvd., Paiin Kouh Road, Islamic Azad University of Zanjan
**City**
Zanjan
**Province**
Zanjan
**Postal code**
4515658145
**Approval date**
2024-04-17, 1403/01/29
**Ethics committee reference number**
IR.IAU.Z.REC.1403.005

## Health conditions studied

**1**

**Description of health condition studied**
Coronary artery diseases
**ICD-10 code**
I25.1
**ICD-10 code description**
Atherosclerotic heart disease of native coronary artery

## Primary outcomes

**1**

**Description**
Matrix Metalloproteinases 1، 2، 3 and 9
**Timepoint**
beginning and end of the eight-week experimental period
**Method of measurement**
Sampling of venous blood

**2**

**Description**
tissue inhibitor of Matrix Metalloproteinases 1
**Timepoint**
beginning and end of the eight-week experimental period
**Method of measurement**
Sampling of venous blood

## Secondary outcomes

**1**

**Description**
Heart rate of subjects during exercise training
**Timepoint**
At the beginning, during and at the end of each exercise training session
**Method of measurement**
Using the cardiac monitoring device with the subjects

**2**

**Description**
Systolic and diastolic blood pressure of subjects during exercise
**Timepoint**
At the beginning and at the end of each exercise training session
**Method of measurement**
Using an analog blood pressure monitor

## Intervention groups

**1**

**Description**
Intervention group: First group: eight weeks of aerobic training, second group: eight weeks of vitamin E and C supplements(1000 mg of D-Alpha Tocopherol Tablets by Life Plan Company per day and 1000 mg of Vitamin C Borrow made by Omid Persian Damavand Company per day), third group: eight weeks of aerobic training along with vitamin E and C supplements(1000 mg of D-Alpha Tocopherol Tablets by Life Plan Company per day and 1000 mg of Vitamin C Borrow made by Omid Persian Damavand Company per day).
**Category**
Rehabilitation

**2**

**Description**
Control group: During eight weeks, they will not experience any intervention of antioxidant drugs and training.
**Category**
Rehabilitation

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Bahman hospital
**Full name of responsible person**
Mahdi Rezagholizadeh
**Street address**
Behind Rozbeh University, Poonak town, 22 Bahman Highway
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Islamic Azad University, Rasht Branch
**Full name of responsible person**
Ramin Shabani
**Street address**
Lacan Gate, Islamic Azad University, Rasht Branch
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**Province**
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**Fax**
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**Email**
iaurasht.ac@gmail.com
**Web page address**
https://rasht.iau.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Islamic Azad University, Rasht Branch
**Proportion provided by this source**
10
**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, Zanjan Branch
**Full name of responsible person**
Mahdi Rezagholizadeh
**Position**
Assistant Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Exercise Physiology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**
Assistant Professor

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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**
consult with other project colleagues

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

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

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

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