

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of supplementation beetroot capsul with or without vitamin C on serum fatty acids and oxidative stress factors in patients with chronic coronary heart disease. Double blind Randomized trial

Protocol summary

Study aim

Effect of supplementation beetroot capsul with vitamin C on serum fatty acids and oxidative stress factors in patients with chronic coronary heart disease

Design

This is a double-blind randomized clinical trial study performed on 90 men and women aged 30 to 65 years with coronary heart disease. Two intervention groups and one control group are parallel. Phase 3 on 90 patients. To apply randomization, the permuted block randomization method with quadruple blocks will be used. 23 blocks of 4 will be produced using the online site (www.sealedenvelope.com).

Settings and conduct

Imam Reza Hospital Candidates are randomly divided into 3 groups receiving medication and placebo. At the beginning of the study, 10 ml of venous blood sample is taken from each person in the fasting state. Concealed allocation using opaque envelopes, in closed, sealed and sequential (double-blind random)

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age 30 to 65 years 2. Men and women with chronic coronary artery disease 3. Willingness to participate in research
Exclusion criteria: 1. Do not consume more than 10% of capsules 2. The occurrence of any accident that affects a person's health 3. Having any acute illness during the study 4. Reluctance to continue cooperation in research

Intervention groups

Two groups of drug recipients: 1- 30 men and women with coronary heart disease, 4 weeks intervention, three 500 mg capsules of red beet daily 2- 30 men and women with coronary heart disease, 4 weeks intervention, three 500 mg capsules of red beetroot and vitamin C daily. Placebo group: 30 men and women with coronary heart disease, 4 weeks intervention, three placebo capsules daily.

Main outcome variables

Saturated fatty acids (SFAs), Unsaturated fatty acids (UFAs), Total antioxidant capacity (TAC), Total oxidative status (TOS), malondialdehyde (MDA), myeloperoxidase (MPO)

General information

Reason for update

The addition of primary outcome and new factors in the analysis of blood samples

Acronym

IRCT registration information

IRCT registration number: **IRCT20210217050393N3**

Registration date: **2022-07-28, 1401/05/06**

Registration timing: **prospective**

Last update: **2023-07-27, 1402/05/05**

Update count: **1**

Registration date

2022-07-28, 1401/05/06

Registrant information

Name

REZA REZVANI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2418

Email address

rezvanir@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of supplementation beetroot capsul with or without vitamin C on serum fatty acids and oxidative stress factors in patients with chronic coronary heart disease.
Double blind Randomized trial

Public title

Effect of supplementation beetroot capsul with or without vitamin C on oxidative stress factors in patients with chronic coronary heart disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Age 30 to 65 years 2. Men and women with chronic coronary artery disease 3. Willingness to participate in research

Exclusion criteria:

1. Do not consume more than 10% of capsules 2. The occurrence of any accident that affects a person's health 3. Having any acute illness during the study 4. Reluctance to continue cooperation in research 5. Body Mass Index more than 30 kg / m² 6. Acute heart accident in the past year 7. Taking any medicine outside the treatment protocol 8. Consumption of any herbal medicines 9. Allergy to red beet 10. Nitrate-containing drugs (such as nitroglycerin, isosorbide) 11. Using oral and injectable nutritional supplements for at least the last 4 months (vitamins D, C, E, calcium, magnesium, potassium and multivitamin-mineral, omega 3) 12. Disease (diabetes, kidney stones, gallstones, cancer and other chronic diseases)

Age

From 35 years old to 65 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: 90

More than 1 sample in each individual

Number of samples in each individual: 2

10 ml venous blood sample / Anthropometric variables

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization To apply randomization, the method of permuted block randomization with quadruple

blocks will be used. In order to apply concealment in the randomization process, unique codes will be used on drug boxes, and the desired code will also be used by the online site. it is produced. Concealed allocation using opaque envelopes, in closed, sealed and sequential

Blinding (investigator's opinion)

Double blinded

Blinding description

Concealed allocation using opaque envelopes, in closed, sealed and sequential. Participants (lack of knowledge of intervention groups), Care providers (lack of knowledge of sample type assignment to groups), Investigator

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

faculty of Medicine, East door of Ferdowsi University, Mashhad, Khorasan Razavi, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2022-05-31, 1401/03/10

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.157

Health conditions studied**1****Description of health condition studied**

Coronary heart disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes**1****Description**

Malondialdehyde

Timepoint

At the beginning of the study and 28 days after consume red beet capsules
Method of measurement
laboratory kit

2

Description

Myeloperoxidase

Timepoint

At the beginning of the study and 28 days after consume red beet capsules

Method of measurement

laboratory kit

3

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and 28 days after consume red beet capsules

Method of measurement

laboratory kit

4

Description

Total Oxidant Status

Timepoint

At the beginning of the study and 28 days after consume red beet capsules

Method of measurement

laboratory kit

5

Description

Saturated fatty acids

Timepoint

At the beginning of the study and 28 days after consume red beet

Method of measurement

Gas Chromatography

6

Description

Polyunsaturated fatty acids

Timepoint

At the beginning of the study and 28 days after consume red beet

Method of measurement

Gas Chromatography

7

Description

Monounsaturated fatty acids

Timepoint

At the beginning of the study and 28 days after consume red beet

Method of measurement

Gas Chromatography

8

Description

Fatty acid indices

Timepoint

At the beginning of the study and 28 days after consume red beet

Method of measurement

Calculation through other fatty acids

Secondary outcomes

1

Description

Waist circumference

Timepoint

At the beginning of the study and 28 days after the intervention

Method of measurement

tape measure

2

Description

Hip circumference

Timepoint

At the beginning of the study and 28 days after the intervention

Method of measurement

tape measure

3

Description

Neck circumference

Timepoint

At the beginning of the study and 28 days after the intervention

Method of measurement

tape measure

4

Description

Weight

Timepoint

At the beginning of the study and 28 days after the intervention

Method of measurement

Bioelectrical Impedance Analysis(BIA)

5

Description

Fat mass

Timepoint

At the beginning of the study and 28 days after the intervention

Method of measurement

Bioelectrical Impedance Analysis(BIA)

6

Description

Free fat mass

Timepoint

At the beginning of the study and 28 days after the intervention

Method of measurement

Bioelectrical Impedance Analysis(BIA)

7

Description

Body Mass Index(BMI)

Timepoint

At the beginning of the study and 28 days after the intervention

Method of measurement

Bioelectrical Impedance Analysis(BIA)

Intervention groups

1

Description

Intervention group1: 30 men and women with coronary heart disease received three 500 mg red beet capsules daily for 4 weeks each.

Category

Treatment - Drugs

2

Description

Intervention group 2 : 30 men and women with coronary heart disease received three 500 mg capsules of red beets and vitamin C daily for 4 weeks each.

Category

Treatment - Drugs

3

Description

Control group: Control group: 30 men and women with coronary heart disease received three placebo capsules a day for 4 weeks each, which is very similar in appearance and volume to the drug capsule.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Reza Rezvani

Street address

Imam Reza Square, Ibn Sina St, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9191-991778

Phone

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Email

rezvanir@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour Mobarhan

Street address

Mashhad university of medical sciences, Azadi square

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Postal code

9138813944

Phone

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Email

GhayourM@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Reza Rezvani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Reza Rezvani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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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

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