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
+98 51 3841 2081
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 squre
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
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

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Person responsible for scientific inquiries

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Position
Assistant Professor
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Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Reza Rezvani
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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rezvanir@mums.ac.ir

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