Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of red beetroot tablet alone or in combination with vitamin C on cardiovascular function in patients with chronic coronary heart disease. Double blind Randomized clinical trial.

Protocol summary

Study aim

Evaluation of the effect of concentrated red beet tablets alone or in combination with vitamin C on cardiovascular function, respiratory function and improvement of clinical symptoms in patients with chronic coronary heart disease

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 90 patients. The online site (www.sealedenvelope.com) was used for randomization.

Settings and conduct

The present study will be performed in Imam Reza Hospital and people who have the necessary criteria for entering the project in 1401-1400. Volunteers are randomly divided into three groups of drug and placebo recipients. 10 ml of intravenous blood sample is taken from each volunteer during fasting. Anthropometric, volumetric, echocardiographic and cardiovascular data are also collected. Questionnaires related to physical activity, 24-hour recall, quality of life and health will also be completed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 30 to 65 years, men and women with chronic coronary artery disease, willingness to participate in research Exclusion criteria: body mass index above 30 kg / m2, chronic disease, acute heart accident in the past year, taking medication outside the treatment protocol, beet allergy, taking drugs containing nitrate, unwillingness to continue cooperation in research, not taking more than 10% of pills

Intervention groups

The intervention group includes the group receiving tablets containing concentrated red beets, the group receiving tablets containing concentrated red beets with vitamin C three daily for 6 weeks, and the control group receiving placebo tablets three daily for 6 weeks.

Main outcome variables

Flow Mediate Dilation, Pulse Wave Velocity, Augmentation Index, hs-C Reactive Protein, Interleukin-6, Intercellular adhesion molecule,vascular cell adhesion molecule

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210217050393N1**
Registration date: **2021-05-16, 1400/02/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-16, 1400/02/26**
Update count: **0**

Registration date

2021-05-16, 1400/02/26

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

2021-04-21, 1400/02/01

Expected recruitment end date

2021-12-21, 1400/09/30

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

Scientific title
Evaluation of the effect of red beetroot tablet alone or in combination with vitamin C on cardiovascular function in patients with chronic coronary heart disease. Double blind Randomized clinical trial.

Public title
Evaluation of the effect of red beet in patients with chronic coronary heart disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 30 to 65 years male and female with chronic coronary artery disease Willingness to participate in research
Exclusion criteria:
Body Mass Index more than 30 kg / m2 Disease (diabetes, kidney stones, gallstones, cancer and other chronic diseases) Acute heart accident in the past year Taking any medicine outside the treatment protocol 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) Consumption of any herbal medicines Allergy to red beet Pregnancy and breastfeeding Smoking and drugs Alcohol consumption Nitrate-containing drugs (such as nitroglycerin, isosorbide) The occurrence of any accident that affects a person's health Having any acute illness during the study Reluctance to continue cooperation in research Do not take more than 10% of tablets
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
More than 1 sample in each individual
Number of samples in each individual: **30**
Drug group: 30 men and women with coronary heart disease, each for 6 weeks, will receive three 1000 mg beetroot tablets daily, 30 men and women with coronary heart disease, each Which will receive three 1000 mg beetroot and vitamin C tablets daily for 6 weeks. Placebo group: 30 men and women with coronary heart disease will receive three placebo tablet each day for 6 weeks, which is very similar in appearance and volume to nitrate tablets.
Randomization (investigator's opinion)
Randomized
Randomization description
To apply randomization, the permuted block randomization method with quadruple blocks will be used. According to the sample size of 90 that has been determined, 18 blocks of 5 will be produced using the online site (www.sealedenvelope.com). In order to apply concealment in the randomization process, unique codes will be used on the medicine boxes, and the desired code will also be generated by the online site. Concealed allocation is done using opaque envelopes, in packages, sealed and sequentially.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In order to apply blinding in the randomization process, unique codes will be used on the medicine boxes, and the desired code will also be produced by the online site. In the present study, participants, principle investigator , healthcare providers, outcome assessors will be blinded.
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
Mashhad university of medical sciences, Azadi squre
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2020-09-22, 1399/07/01
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.717

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
Pulse Wave Velocity
Timepoint
before and after intervention
Method of measurement
with pulse velocimetry

2

Description
augmentation index
Timepoint
before and after intervention
Method of measurement
with pulse velocimetry

3

Description
flow mediate dilation
Timepoint
before and after intervention
Method of measurement
with pulse velocimetry

4

Description
VO2max
Timepoint
before and after intervention
Method of measurement
CPET device

5

Description
lipid profile
Timepoint
before and after intervention
Method of measurement
blood test

6

Description
Interleukin 6
Timepoint
before and after intervention
Method of measurement
blood test

7

Description
high sensitive-C Reactive Protein
Timepoint
before and after intervention
Method of measurement
blood test

8

Description
Intercellular-adhesion molecule (I-CAM)
Timepoint
before and after intervention
Method of measurement
blood test

9

Description
vascular cell adhesion molecule (VCAM)
Timepoint
before and after intervention
Method of measurement
blood test

10

Description
systolic blood pressure
Timepoint
before and after intervention
Method of measurement
Sphygmomanometer

11

Description
diastolic blood pressure
Timepoint
before and after intervention
Method of measurement
Sphygmomanometer

Secondary outcomes

1

Description
weight
Timepoint
before and after intervention
Method of measurement
digital scale

2

Description
Waist circumference
Timepoint
Before and after the intervention
Method of measurement
Non-elastic meters

3

Description
neck circumference
Timepoint
Before and after the intervention
Method of measurement
Non-elastic meters

4

Description
Waist to hip ratio
Timepoint
Before and after the intervention
Method of measurement
Waist to hip ratio

5

Description
Body Shape Index
Timepoint
Before and after the intervention
Method of measurement
waist circumference/ body mass index 2/3* height 1/2

6

Description
body mass index
Timepoint
Before and after the intervention
Method of measurement
weight/(height)2

7

Description
Quality of life and health
Timepoint
Before and after the intervention
Method of measurement
SF36 questionnaire

Intervention groups

1

Description
Intervention group 1: Three 1000 mg tablets of concentrated red beet daily (containing 22 mg of nitrate as active ingredient and other compounds including betalines, carotenoids, phenolic acids and flavonoids, which in the initial phase of the present project were Prepared beetroot powder with freeze drier method and produced in the form of tablets), will intervene for 6 weeks
Category
Treatment - Drugs

2

Description
Intervention group 2: Three 1000 mg contain beetroot and 100 mg vitamin C tablets daily for 6 weeks
Category
Treatment - Drugs

3

Description
Control group: Three 1000 mg placebo tablets (Starch with edible color of red beets) daily for 6 weeks
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 Hospital, Ebne Sina Street
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9191-991778
Phone
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Email
rezarezvani991@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Mashhad university of medical sciences, Azadi squre
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tafaghodim@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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Person responsible for updating data

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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
There is no further information
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