

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 square

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 $2/3 \times$ 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

City

Mashhad

Province

Razavi Khorasan

Postal code

9191-991778

Phone

+98 51 3841 2081

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 square

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

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

Street address

Mashhad university of medical sciences, Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

99191-91778

Phone

+98 51 3841 2081

Email

rezvanir@mums.ac.ir

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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Phone

+98 51 3841 2081

Email

rezvanir@mums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Reza Rezvani

Position

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Latest degree

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Phone

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Email

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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