

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigation of the effect of two weeks supplementation with red Beet root and Prickly pear aqueous extract powder on the plasma Sirtuin 1 and homocysteine concentrations, SIRT-1 and LOX-1 gene expressions, and lipids profile in overweight and obese male patients with Coronary Heart Disease.

Protocol summary

Study aim

The purposes of this study is to investigate the effects of consumption of two edible sources of betalain (red beetroot and prickly pear) on LOX1 and SIRT1 gene and protein expression and some of the atherosclerotic risk factors in patients with coronary heart disease (CHD).

Design

double-blinded crossover randomized clinical trial

Settings and conduct

Participants were recruited from cardiologist referrals from Tabriz Shahid Madani medical research training Center. Other parts of this study is carried out at Tabriz University of Medical Sciences and Tarbiat Modares University. In this study, all relevant people except the investigator are blind to the study groups.

Participants/Inclusion and exclusion criteria

obese or overweight male patients (50 ± 5 y; BMI = 30 ± 5 kg/m²) with coronary heart disease

Intervention groups

Part 1: Consumption of a single dose of 50 mg of betacyanins and of betaxanthins (purified from red beetroot extract) by same 48 patients Part 2: At first, patients will randomly be allocated to 2 study arms where each arm will consist of a sequence of three treatments given consecutively. The first group will receive capsules of red beetroot (contained 25 mg betalain) for two weeks, followed by two weeks wash out, and after that, for two weeks they received capsules of *Opuntia stricta* (contained 25 mg betacyanin), followed by two weeks wash out and finally, for two weeks they received placebo capsule, and vice versa in the second group. Participants of both groups will be requested to take 1 capsules two times daily.

Main outcome variables

Measurement of Sirtuin-1 and Lectin-like oxidized low-density lipoprotein receptor 1 genes expression, and plasma levels of Sirtuin-1 protein are primary outcomes and blood pressure and fasting blood glucose, lipid profile, C-reactive protein, and homocysteine betalain profile of blood and urine are the secondary outcomes.

General information

Reason for update

Acronym

CVD CHD

IRCT registration information

IRCT registration number: **IRCT2017092836469N1**

Registration date: **2017-11-20, 1396/08/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-01, 1397/12/10**

Update count: **3**

Registration date

2017-11-20, 1396/08/29

Registrant information

Name

Rahimi Parisa

Name of organization / entity

Tarbiat Modares University

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Recruitment status

Recruitment complete

Funding source

Tarbiat Modares University Tabriz University of Medical Science

Expected recruitment start date

2017-11-01, 1396/08/10

Expected recruitment end date

2018-06-17, 1397/03/27

Actual recruitment start date

2017-11-14, 1396/08/23

Actual recruitment end date

2018-09-18, 1397/06/27

Trial completion date

empty

Scientific title

Investigation of the effect of two weeks supplementation with red Beet root and Prickly pear aqueous extract powder on the plasma Sirtuin 1 and homocysteine concentrations, SIRT-1 and LOX-1 gene expressions, and lipids profile in overweight and obese male patients with Coronary Heart Disease.

Public title

supplementation in coronary heart disease

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Men Diagnosed with Coronary heart patients 45-55 y of old BMI (in kg/m²) of 25-35 No tobacco or alcohol consumption free of any serious and life-threatening illness, Malignancy, Cancer, Diabetes, Autoimmune disease, Infectious diseases, Anemia and with no stone maker kidney or bladder Subjects with no history of allergic reaction to beetroot or prickly pear No changes in drug administration (patients only consume typically administered drugs for hypertension or dyslipidemia) Subjects with no recent or current consumption of interventional supplements Patients will be enrolled following an informed consent.

Exclusion criteria:

Myocardial Infarction Strenuous exercise Fasting Allergic reactions Any exposure or catch of infectious disease Any side effect Subjects with recent or current taking systemic medication (other than the usual drug for hypertension and dyslipidemia) Patients with Failure to execute commands Healthy subjects unwilling to consent

Age

From **45 years** old to **55 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **24**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are classified into two groups by random block method. A random sequence is generated using the STATA14 software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, all relevant people (participants, care provider, outcome assessor, data analyzer, and data safety and monitoring board) except the investigator, are blind using the coding system before starting intervention. Researchers who involved in the writing of paper and final conclusion would have permission to access decoded information in order to have the best interpretations and scientific results.

Placebo

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

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

Ethics committee of Tarbiat Modares University

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Tehran, Jalal AleAhmad , Nasr

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Postal code

14115-111

Approval date

2017-09-23, 1396/07/01

Ethics committee reference number

IR.TMU.REC.1396.609

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

Atherosclerotic Coronary Heart disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

Sirtuin-1 gene

Timepoint

days: 0, 14, 28, 42, 56, 70, and after single dose consumption in part 2 of study

Method of measurement

expression measurement with Real-Time PCR

2

Description

Lectin-like oxidized low density lipoprotein receptor-1 gene

Timepoint

days: 0, 14, 28, 42, 56, 70, and after single dose consumption in part 2 of study

Method of measurement

expression measurement with Real-Time PCR

3

Description

sirtuin-1 protein

Timepoint

days: 0, 14, 28, 42, 56, 70, and after single dose consumption in part 2 of study

Method of measurement

Concentration measurement with ELIZA

Secondary outcomes

1

Description

Fasting Blood Glucose

Timepoint

days: 0, 14, 28, 42, 56, 70

Method of measurement

spectrophotometric assay and autoanalyzer

2

Description

Blood pressure

Timepoint

days: 0, 14, 28, 42, 56, 70, and after single dose consumption in part 2 of study

Method of measurement

digital blood pressure monitor

3

Description

Homocystein

Timepoint

days: 0, 14, 28, 42, 56, 70

Method of measurement

Concentration measurement with ELIZA

4

Description

Lipid profile

Timepoint

days: 0, 14, 28, 42, 56, 70

Method of measurement

Concentration measurement with Enzyme, Autoanalyzer and formula

5

Description

C-reactive protein

Timepoint

days: 0, 14, 28, 42, 56, 70

Method of measurement

Concentration measurement with ELIZA

6

Description

Health related quality of life

Timepoint

days: 0, 14, 28, 42, 56, 70

Method of measurement

MacNew questionnaire

7

Description

Hulbert Index of Sexual Desire (HISD)

Timepoint

days: 0, 14, 28, 42, 56, 70

Method of measurement

questionnaire

8

Description

Dietary intake and appetite assessment

Timepoint

weekly

Method of measurement

questionnaire

9

Description

Beck Depression Inventory II (BDI-II)

Timepoint

days: 0, 14, 28, 42, 56, 70

Method of measurement

questionnaire

10

Description

Plasma and urine profile of betalains

Timepoint

days: 0, 14, 28, 42, 56, 70, and after single dose consumption in part 2 of study

Method of measurement

High-performance liquid chromatography-tandem mass

Intervention groups

1

Description

Part1: Consumption of a single dose of 50 mg of betacyanins and of betaxanthins (purified from red beetroot extract) by patients. Part2: The first group (n=24) receive one 500mg-capsule of betalains-rich extract of red beetroot (the freeze-dried powders containing 5% betalain, prepared from fresh red beetroot juice. This powder is containing 25 mg betalain, a little sugar, protein and depleted of fiber) two times daily; for 2 weeks, followed by two weeks wash out. After that, they receive one 500mg-capsule of betacyanins-rich extract of prickly pear (the freeze-dried powders containing 5% betalain, prepared from fresh red-purple Opuntia stricta fruit. This powder is containing 25 mg betacyanins, a little sugar, protein and depleted of fiber) two times daily; for 2 weeks, followed by two weeks wash out. After that, they receive one placebo capsules, two times daily; for two weeks.

Category

Treatment - Other

2

Description

Part 1: Consumption of a single dose of 50 mg of betacyanins and of betaxanthins (purified from red beetroot extract) by patients Part 2: The first group (n=24) receive one 500mg-capsule of betacyanins-rich extract of prickly pear (the freeze-dried powders containing 5% betalain, prepared from fresh red-purple Opuntia stricta fruit. This powder is containing 25 mg betacyanins, a little sugar, protein and depleted of fiber) two times daily; for 2 weeks, followed by two weeks wash out. After that, they receive one 500mg-capsule of betalains-rich extract of red beetroot (the freeze-dried powders containing 5% betalain, prepared from fresh red beetroot juice. This powder is containing 25 mg betalain, a little sugar, protein and depleted of fiber) two times daily; for 2 weeks, followed by two weeks wash out. After that, they receive one placebo capsules, two times daily; for two weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madany Medical Research Training center,
Tabriz university of medical science

Full name of responsible person

Rahimi Parisa, PhD. student in clinical biochemistry---
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tarbiat Modares
University, Faculty of medical science

Full name of responsible person

Dr Mesbah-Namin Alireza

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Tarbiat Modares
University, Faculty of medical science

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
Tarbiat Modares University
Full name of responsible person
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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)
Undecided - It is not yet known if there will be a plan to make this available
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
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available