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

Country

Iran (Islamic Republic of)

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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
Street address
Tehran, Jalal AleAhmad , Nasr
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Province
Tehran
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

spectrometry (HPLC–MS/MS)

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---Dr. Separham Ahmad, Cardiologist and Associat

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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
Rahimi Parisa
Position
student at Clinical Biochemistry
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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