Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of the effect of saffron aqueous extract and its carotenoids (crocin and crocetin) on plasma proteome pattern, expression of LOX1 gene and miRNA223, and serum homocystein levels in atherosclerotic patients.

Protocol summary

Study aim

Investigation of the effects of saffron aqua-extraction and its carotenoids (crocin and crocetin) on the fasting blood glucose (FBG), lipid profile, and serum concentration of homocysteine, MCP-1, ICAM-1, VCAM-1, and h-FABP and genes expressions of SIRT1, LOX-1, MCP-1, AMPK, NFκB, and miR-223 and anthropometric indices, quality of life assessment, left ventricular ejection fraction and the plasma proteomic pattern in atherosclerotic patients in comparison with together and control group.

Design

A double-blinded parallel randomized clinical trial with 89 patients and at phase 2

Settings and conduct

This study is done in the Shahid Madani Cardiovascular Center of Tabriz. Biochemical and Proteomics tests will be carried out at Tarbiat Modarres University. Before and after interventions, blood samples will be collected. A part of the plasma will be deabuminated and be applied for two-dimensional gel electrophoresis. Then, the plasma proteome patterns of the patients before and after intervention will be compared using a software. ELISA, Colorimetry, and Real-Time PCR will be used for Measuring of serum concentration of homocysteine and proteins, lipid profile and FBG, and genes expressions, respectively. Finally, all data will be analyzed via suitable statistical analysis methods.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Overweight/obese CAD patients of both gender (45-60 year old, BMI: 25-35 Kg/m2) Exclusion criteria: Cardiac events, Gestation, Menopause

Intervention groups

89 patients in 4 groups will randomly receive one capsule containing saffron aqua extract (30 mg; N: 20) or crocin (30 mg; N: 24) or crocetin (10 mg, N: 24) or placebo (N: 21), once a day, for 60 days.

Main outcome variables

FBG lipid profile Plasma concentrations of Hcy, MCP-1, ICAM-1, VCAM-1, h-FABP Genes expressions of SIRT1, LOX-1, MCP-1, AMPK, NFκB, miR-223 LVEF Proteomic pattern

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161102030649N1**
Registration date: **2018-01-26, 1396/11/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-17, 1397/11/28**
Update count: **2**

Registration date

2018-01-26, 1396/11/06

Registrant information

Name
Saeed Abedimanesh
Name of organization / entity
Tarbiat Modares University
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-06, 1396/12/15

Actual recruitment start date

2017-09-24, 1396/07/02

Actual recruitment end date

2018-03-15, 1396/12/24

Trial completion date

2018-03-15, 1396/12/24

Scientific title

Study of the effect of saffron aqueous extract and its carotenoids (crocin and crocetin) on plasma proteome pattern, expression of LOX1 gene and miRNA223, and serum homocystein levels in atherosclerotic patients.

Public title

Effect of saffron aqua-extract and its carotenoids in atherosclerotic patients.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

subjects with coronary artery disease 40-65 years old overweight and obese (BMI 25-35 kg/m2) subjects without a history of myocardial infarction (MI) No tobacco or alcohol consumption who had no symptoms of cancer, auto-immune, allergy, infection, kidney and liver diseases Not consuming of antioxidants supplement and vitamins for the last six months. Signing up the informed consent form

Exclusion criteria:

Cardiac events Gestation or Menopause Recent taking systemic medication (other than the usual drug for hypertension, dyslipidemia, and hyperglycemia)

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

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

Sample size

Target sample size: **60**

Actual sample size reached: **89**

Randomization (investigator's opinion)

Randomized

Randomization description

randomization will be done with software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients, investigators who administer drug/placebo to patients, statistical and laboratory analyzer technicians as well as healthcare center personnel, 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

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tarbiat Modares University

Street address

Tarbiat Modares University, Gisha Bridg, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

14115-116

Approval date

2017-09-23, 1396/07/01

Ethics committee reference number

IR.TMU.REC.1396.610

Health conditions studied

1

Description of health condition studied

Cardiovascular disease, coronary artery disease (CAD)

ICD-10 code

I25.110

ICD-10 code description

Atherosclerotic heart disease of native coronary artery with unstable angina pectoris

Primary outcomes

1

Description

LOX-1 gene relative expression in PBMCs.

Timepoint

Before the intervention (day 0), and 8 weeks after the intervention (day 60)

Method of measurement

Real time PCR

2

Description

miRNA-223 copy number in PBMCs

Timepoint

Before the intervention (day 0), and 8 weeks after the

intervention (day 60)
Method of measurement
Real time PCR

3

Description
Plasma Homocystein concentration
Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
ELISA

4

Description
Plasma Proteome patern
Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
2-D Gel Electrophoresis

5

Description
Serum concentrations of h-FABP
Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
ELISA

6

Description
Serum concentrations of MCP-1
Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
ELISA

7

Description
Serum concentrations of ICAM-1
Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
ELISA

8

Description
Serum concentrations of VCAM-1
Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
ELISA

9

Description
fasting blood glucose (FBG)
Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
colorimetric based kit

10

Description
Lipid profile
Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
colorimetric based kit

11

Description
NFκB gene relative expression in PBMCs.
Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
Real time PCR

12

Description
SIRT-1 gene relative expression in PBMCs.
Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
Real time PCR

13

Description
MCP-1 gene relative expression in PBMCs.
Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
Real time PCR

14

Description
AMPK gene relative expression in PBMCs.
Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
Real time PCR

15

Description
left Ventricular Ejection Fraction (LVEF)

Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
Echocardiographic examinations were performed using Vivid 7 Pro (GE, USA) instrument

Secondary outcomes

1

Description
Body Mass Index (BMI)
Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
height and weight measurement and calculate with formula

2

Description
waist to hip circumference (WHR)
Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
spring-loaded tape measure

3

Description
Quality of life assessment
Timepoint
Before the intervention (day 0), and 8 weeks after the intervention (day 60)
Method of measurement
Mac new quality of life questionnaire for ischemic heart patients

Intervention groups

1

Description
Intervention group: 1. In this group of study, each patient receives one capsule of 30 mg saffron aqua-extract (made by Dr. Bathaie Lab. Tarbiat Modares University, Faculty of clinical biochemistry) for 2 months.
Category
Treatment - Other

2

Description
Intervention group: 2. In this group of study, each patient receives one capsule of 30 mg crocin (made by Dr. Bathaie Lab. Tarbiat Modares University, Faculty of clinical biochemistry) for 2 months.
Category
Treatment - Other

3

Description
Intervention group: 3. In this group of study, each patient receives one capsule of 10 mg crocetin (made by Dr. Bathaie Lab. Tarbiat Modares University, Faculty of clinical biochemistry) for 2 months.
Category
Treatment - Other

4

Description
Control group: 4. In this group of study, each patient receives one placebo capsule (made by Dr. Bathaie's Lab. Tarbiat Modares University, Faculty of clinical biochemistry) for 2 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Medical research training center, Tabriz university of medical science.
Full name of responsible person
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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
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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
Saeed Abedimanesh
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

only primary outcome measure will be shared after intervention.

When the data will become available and for how long

Starting 1 year after publication.

To whom data/document is available

Documents/Information will be shared only for people working in academic institutions.

Under which criteria data/document could be used

Researchers at the field of cardiovascular disease can achieve our documents and information. but they must named our researchers as the co-authors in their publications.

From where data/document is obtainable

Saeed Abedimanesh Tell: 00989141145213 E-mail: s.abedymanesh@modares.ac.ir

What processes are involved for a request to access data/document

Applicants must explain their conditions by email, after acceptance they will receive the documents.

Comments