

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Effect of Supplementation with Crocetin (Saffron carotenoids) on Antioxidant Indices, Inflammatory index and Serum Leptin Concentration in Patients with Coronary Artery Diseases: A Double-Blind Randomized Clinical Trial

Protocol summary

Study aim

To determine the effect of Crostin on antioxidant indices, inflammatory index and serum leptin in coronary artery patients.

Design

Randomised, parallel group trial with blinded outcome assessment. Random numbers generated by Sealed Envelope at an external site.

Settings and conduct

Double-blind randomized clinical controlled trial will be carried out through parallel design, with 50 patients who are diagnosed by a cardiologist in the medical centers of Ahvaz University of Medical Sciences. Patients will be divided into two groups of 25 patients receiving Crocetin and placebo. Patients will receive 1 capsule of 125 mg daily Crocetin (10 mg dry crocetin powder) and placebo that are similar in appearance to the intervention for 8 weeks. Cans containing capsules will be coded by a nonresearcher as allocation concealment and distributed to the patients in each block randomly.

Participants/Inclusion and exclusion criteria

Inclusion : Coronary artery occlusion disease Age 40 to 65 BMI 25-35 Willing to participate Exclusion : Any heart attack Lactation / pregnancy Allergic reactions Incidence of infectious disease or side effect during the study, Taking new medications Irregular usage of intervention capsule Unwillingness to continue

Intervention groups

The patient with block randomization divided into two groups of 25 receiving 125 mg capsule of Crocetin (1 dry 10 mg crostin powder with corn starch filler) and placebo (corn starch) daily. Supplements are given 1 hr before lunch for 8 weeks. All capsules are in the same shape and size.

Main outcome variables

Hs- CRP, Antioxidant indices, leptin level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220902055853N2**

Registration date: **2023-05-18, 1402/02/28**

Registration timing: **prospective**

Last update: **2023-05-18, 1402/02/28**

Update count: **0**

Registration date

2023-05-18, 1402/02/28

Registrant information

Name

fatemeh borazjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3321 9570

Email address

fa.borazjani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-09, 1402/03/19

Expected recruitment end date

2023-12-10, 1402/09/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Supplementation with Crocetin (Saffron carotenoids) on Antioxidant Indices, Inflammatory index and Serum Leptin Concentration in Patients with Coronary Artery Diseases: A Double-Blind Randomized Clinical Trial

Public title
Effect of Saffron in Coronary Artery Diseases

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Coronary artery occlusion disease Willingness to participate in the study Age range of 40 to 65 years BMI 25-35
Exclusion criteria:
Having heart attack lactation or pregnancy Having any infectious disease Chang the usual medications Irregular consumption of interventional capsules Taking food supplement, vitamin and mineral for at least in the last 3 months Participate in another trial simultaneously Having an Allergic reaction to interventional herb

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Method of randomization is blocks.The entry of each patient into the Intervention or Control group is distributed in each group using the Randomization method with the help of four blocks. This work is done by using a sequence of random numbers generated by Sealed Envelope Ltd. 2022. Create a blocked randomization list. [Online] Available from:<https://www.sealedenvelope.com/simple-randomise/r/v1/lists>

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will be double-blinded, hence the researcher and participants will not know which group they are belong to. For blinding, intervention and placebo capsules are provided in similar shapes, colors, and sizes. These capsules are coded (A and B) by a person other than the investigators and then are given to the participants. Until the end of study and after analyzing of data, investigators are not informed about the

intervention and control groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Ahvaz Jundishapur university of medical sciences,Ahvaz,Iran
Street address
University of Medical Sciences and Health Care Services Ahvaz, Research and Technology Development Deputy Building, Nutrition and Metabolic Diseases Research Cente
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2023-04-08, 1402/01/19
Ethics committee reference number
IR.AJUMS.REC.1402.024

Health conditions studied

1

Description of health condition studied
Coronary Artery Diseases
ICD-10 code
I25.1
ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
Hs-CRP
Timepoint
At the beginning and end of study
Method of measurement
Serum sample

Secondary outcomes

1

Description

Superoxide dismutase (SOD)

Timepoint

At the beginning and end of study

Method of measurement

Serum sample

2

Description

Malondialdehyde (MDA)

Timepoint

At the beginning and end of study

Method of measurement

Serum sample

3

Description

Catalase(CAT)

Timepoint

At the beginning and end of study

Method of measurement

Serum sample

4

Description

Leptin

Timepoint

At the beginning and end of study

Method of measurement

Serum sample

5

Description

Plasma atherogenic index

Timepoint

At the beginning and end of study

Method of measurement

Calculated by log (TG/HDL-C)

6

Description

Systolic and Diastolic Blood Pressure

Timepoint

At the beginning and end of study

Method of measurement

Mercury sphygmomanometer

7

Description

Physical activity

Timepoint

At the beginning and end of study

Method of measurement

International Physical Activity Questionnaire

8

Description

Dietary intake (Energy, Carbohydrate, Fat, Protein)

Timepoint

At the beginning and end of study

Method of measurement

Using Nutritionist IV software

9

Description

Weight

Timepoint

At the beginning and end of study

Method of measurement

Weight measured with minimal clothing and no shoes with an accuracy of 0.1 Using a kilogram scale

10

Description

Body mass index

Timepoint

At the beginning and end of study

Method of measurement

Weight in kilograms divided by height in meters squared.kg/m²

Intervention groups

1

Description

Intervention group: supplementation of Crocetin (10 mg dry crocetin powder, 1 capsules of 125 mg daily) one hour before lunch for period of 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Daily 1 capsules of 125 mg containing corn starch one hour before lunch for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical centers of Ahvaz city

Full name of responsible person

Faezeh Moeini Badi

Street address

Golestan Medical Sciences Dormitory, Golestan Boulevard, Ahvaz, Khuzestan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mehrnoosh Zakerkish
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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

Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Faezeh Moeini Badi
Position
MSc student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition

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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

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

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Effect of Supplementation with crocetin (Saffron carotenoids) on Antioxidant Indices, Inflammatory index and Serum Leptin Concentration in Patients with Coronary Artery Diseases

When the data will become available and for how long

After the publication of the article

To whom data/document is available

All

Under which criteria data/document could be used

Study

From where data/document is obtainable

Fatemeh Borazjani

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

E mail

Comments