Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 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 trough parallel design, with 50 patients who are diagnosed by an 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 capsul 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 capsul 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 capsul 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)

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+98 61 3321 9570

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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-randomiser/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 ActivityQuestionnaire

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
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Golestan Medical Sciences Dormitory, Golestan Boulevard, Ahvaz, Khouzestan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Mehrnoosh Zakerkish
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Ahvaz Jundishapur University of Medical Sciences، Deputy of research and technology .Ahvaz, Iran.
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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
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Position
MSc student
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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