Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

The effects of Astaxanthin supplementation on serum levels of Sirtuin1، TNF-α، metabolic parameters, body composition and nutritional status in patients with coronary artery disease.

Protocol summary

Study aim
Determination of the effect of Astaxanthin supplementation on serum levels of Sirtuin1، TNF-α، metabolic parameters and nutritional status in patients with coronary artery disease

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 44 patients. PASS software was used for randomization.

Settings and conduct
Eligible patients will be selected by a cardiologist and will be included in the study Blinding will be done for researchers and patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients in the age range of 65-40 years, 25 <BMI <35, Proof of 50% stenosis in at least one of the coronary arteries on angiography, Ability and willingness to cooperate in the project Exclusion criteria: Smoking, alcohol, and hookah, Hypothyroidism and Hyperthyroidism, Uncontrolled diabetes, History of myocardial infarction Cardiac dysfunction (Class 3 and 4), Valvular heart disease, Kidney failure, Pregnant and lactating women, Taking herbal supplements and antioxidants in the last three months

Intervention groups
The first group will receive 12 mg of astaxanthin per day and the second group will receive (placebo) 12 mg of microcrystalline cellulose per day. The duration of the intervention will be two months. Both groups will receive a weight loss diet (deduction of 500 kcal)

Main outcome variables
serum levels of Sirtuin 1, Tumour Necrosis Factor-alpha (TNF alpha), Lipid profile(LDL-C ،HDL-C ،TGT، TC), insulin, fasting blood sugar and HOMA-IR(Homeostatic Model Assessment for Insulin Resistance)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201227049857N1**
Registration date: **2021-02-19, 1399/12/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-16, 1400/03/26**
Update count: **2**

Registration date
2021-02-19, 1399/12/01

Registrant information
Name
Marzieh Heidari
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-02-17, 1399/11/29
Expected recruitment end date
2021-08-21, 1400/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of Astaxanthin supplementation on serum levels of Sirtuin1، TNF-α، metabolic parameters, body composition and nutritional status in patients with coronary artery disease.

Public title
The effect of astaxanthin supplementation in patients with coronary artery disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age between 65-40 years BMI between 25-35 Proof of 50% stenosis in at least one of the major coronary arteries in angiography Ability, and willingness to collaborate on the project

Exclusion criteria:
Smoking, alcohol and hookah consumption Hypothyroidism and Hyperthyroidism Uncontrolled diabetes History of myocardial infarction Cardiac dysfunction (Class 3 and 4) Valvular heart disease Kidney failure Pregnant and lactating women Taking herbal supplements and antioxidants in the last three months

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals of the two groups will be placed in one of the intervention or control groups, which will be based on blocks created by random allocation software. The random sequence generated is kept in a safe place and performed by an independent person who is blind to the trial during the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
During the study, neither participants nor researchers will know that each person is in the intervention or control group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Attar Neyshabouri Av., Golgasht St.

City
Tabriz

Province
East Azarbaijan

Postal code
5166/15731

Approval date
2021-02-16, 1399/11/28

Ethics committee reference number
IR.TBZMED.REC.1399.1060

Health conditions studied

1

Description of health condition studied
Coronary Artery Disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Serum level of Sirtuin1

Timepoint
At the beginning and end of the study after 8 weeks

Method of measurement
Measurement with ELISA kit

2

Description
Serum level TNF-∝

Timepoint
At the beginning and end of the study after 8 weeks

Method of measurement
Measurement with ELISA kit

3

Description
Lipid profile

Timepoint
At the beginning and end of the study after 8 weeks

Method of measurement
Enzyme kits and the Friedwald equation

4

Description
Glycemic indexes
Timepoint
At the beginning and end of the study after 8 weeks
Method of measurement
ELISA and spectrophotometer

5

Description
Anthropometric Indices
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of height and weight without shoes and with minimum clothes on, by Seca stadiometer and scale, respectively. Measurement of the waist and hip circumference by a tape measure and body mass index (BMI) by dividing weight (kg) by height squared (m2) and measurement of body composition

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Description
Oxidative stress indices
Timepoint
At the beginning and end of the study after 8 weeks
Method of measurement
Measurement of serum levels of Total antioxidant capacity (TAC) and malondialdehyde (MDA) and Superoxide dismutase by spectrophotometry

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Description
plasminogen activator inhibitor-1
Timepoint
At the beginning and end of the study after 8 weeks
Method of measurement
Measurement with ELISA kit

Secondary outcomes

1

Description
Physical activity level
Timepoint
At the begening and end of the intervention
Method of measurement
Via IPAQ questionnaire

2

Description
Quality of life
Timepoint
At the beginning and end of the study after 8 weeks
Method of measurement
Via MacNew questionnaire

3

Description
depression severity
Timepoint
At the beginning and end of the study after 8 weeks
Method of measurement
Beck Depression Inventory scale

4

Description
blood pressure
Timepoint
At the beginning and end of the study after 8 weeks
Method of measurement
Using a mercury barometer

Intervention groups

1

Description
Intervention group:
Category
Treatment - Drugs

2

Description
Control group:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Medical Research Training Center
Full name of responsible person
Dr mohammad alizadeh
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Daneshgah street, Shahid Madani Medical Research Training Center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Marzieh heidari

Position
Msc student of clinical nutrition

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Other areas of specialty/work
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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

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