

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

**The effects of Astaxanthin supplementation on serum levels of Sirtuin1, TNF- $\alpha$ , 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- $\alpha$ , 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

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3348 1180

##### Email address

mheidari.96@yahoo.com

#### 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- $\alpha$ , 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- $\alpha$

#### 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 (m<sup>2</sup>) and measurement of body composition

## 6

### **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

## 7

### **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 beginning 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

#### **Street address**

Daneshgah street, Shahid Madani Medical Research Training Center

#### **City**

Tabriz

#### **Province**

East Azarbaijan

#### **Postal code**

5166614711

#### **Phone**

+98 41 3335 7581

#### **Fax**

+98 41 3334 0634

#### **Email**

mdalizadeh@tbzmed.ac.ir

## **Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Samiei

**Street address**

Vice Chancellor for Research No 2 Central Building,  
Tabriz University of Medical Sciences, Daneshgah  
Street, Tabriz

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**Email**

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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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Golgasht street, Tabriz university of medical sciences

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr mohammad alizadeh

**Position**

professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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### Person responsible for updating data

**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr mohammad alizadeh

**Position**

professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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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