

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

A clinical trial to compare the effect of supplement containing Astaxanthin and alpha linolenic acid with placebo on serum levels of leptin and adiponectin, hs-CRP, miocardio vascular adhesion factors, nitric oxide and lipid profile in patients with mild to moderate coronary artery stenosis

Protocol summary

Summary

The aim of this study is to determine a synergic effect of Astaxanthin and alpha linolenic acid on some of the inflammation cytokines markers, lipid profile, serum levels of leptin and adiponectin in patients with mild to moderate coronary artery stenosis. Design: This is a double-blind clinical trial including 44 patients with Cardiovascular disease, who will be referred to the Golestan hospital' clinic. Subjects will be followed for a period of 8 weeks. Setting, conduct and participants: 44 patients aged over 18 years with 30 -70 percent stenosis in coronary artery who do not have a specific disease ,will be enrolled in this study. Patients will be randomly divided into two groups using random numbers table. Those patients who do not meet study requirements during the study will be excluded. Interventions: The case group (included 22 patients) will receive a supplement containing of 4mg Astaxanthin and 300 mg alphaslinolenic acid, one tablet daily and the control group (included 22 patients) will use placebo tablets, one tablet daily for 8 weeks. To assess the dietary factors affecting the inflammatory parameters in patients, the total amount of energy, macronutrients and micronutrients will be determined at the beginning and the end of the study. For this purpose three-day recall food questionnaire will be completed by the expert in nutrition science. Patients' weight will be measured with minimal clothes, without shoes by a digital scale. Main outcome measures: The main variables including body fat percentage; blood pressure and biochemical parameters will be measured and reported at the beginning and the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050327727N1**

Registration date: **2017-02-09, 1395/11/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-09, 1395/11/21

Registrant information

Name

Elmira Yousefi

Name of organization / entity

Ahvaz Jundishapour University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 61 3416 4726

Email address

yousefi.e@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Science

Expected recruitment start date

2016-06-28, 1395/04/08

Expected recruitment end date

2017-06-10, 1396/03/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A clinical trial to compare the effect of supplement containing Astaxanthin and alpha linolenic acid with placebo on serum levels of leptin and adiponectin, hs-CRP, miocardio vascular adhesion factors, nitric oxide and lipid profile in patients with mild to moderate coronary artery stenosis

Public title
effect of supplement containing Astaxanthin and alpha linolenic acid in coronary artery stenosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Willingness to participate in the study; age range over 18 years; Patients who are suffering from ischemic heart disease with 30 -70 percent stenosis and are not candidates for coronary angioplasty. Exclusion criteria: having chronic disease; Blood or immunologic disorders; Hypothyroidism; Cardiogenic shock; Myocardial infarction with elevation of ST-segment; Pregnant and lactating women.

Age
From **18 years** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Ethics Committee, Ahvaz Jundishapur University of Medical Sciences, Golestan Ave, Khuozestan, Ahvaz

City
Ahvaz

Postal code

Approval date
2016-10-25, 1395/08/04

Ethics committee reference number
IR.AJUMS.REC.1395.451

Health conditions studied

1

Description of health condition studied
Cardiovascular disease

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease

Primary outcomes

1

Description
Adiponectin

Timepoint
Befor intervention and two months after intervention

Method of measurement
ELISA Test

2

Description
Leptin

Timepoint
Befor intervention and two months after intervention

Method of measurement
ELISA Test

3

Description
vascular cell adhesion molecule 1

Timepoint
Befor intervention and two months after intervention

Method of measurement
ELISA Test

4

Description
E-selectin

Timepoint
Befor intervention and two months after intervention

Method of measurement
ELISA Test

5

Description

C-reactive protein

Timepoint

Before intervention and two months after intervention

Method of measurement

ELISA Test

6

Description

Nitric Oxide

Timepoint

Before intervention and two months after intervention

Method of measurement

ELISA Test

7

Description

Malondialdehyde

Timepoint

Before intervention and two months after intervention

Method of measurement

ELISA Test

8

Description

High-density lipoprotein

Timepoint

Before intervention and two months after intervention

Method of measurement

spectrophotometer Test

9

Description

Low-density lipoprotein

Timepoint

Before intervention and two months after intervention

Method of measurement

spectrophotometer Test

10

Description

Triglycerides

Timepoint

Before intervention and two months after intervention

Method of measurement

spectrophotometer Test

11

Description

Total cholesterol

Timepoint

Before intervention and two months after intervention

Method of measurement

spectrophotometer Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in this group, one oral supplement tablet containing 4 mg of Astaxanthin and 300mg alpha-Linolenic acid, produced in USA is prescribed. It should be used daily for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: in this group, a placebo pill produced in the form of oil capsule by Barij Company containing paraffin, is prescribed. It should be used daily for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Golestan Hospital

Full name of responsible person

Elmira Yousefi

Street address

Clinic, Golestan Hospital, Golestan Ave, Khuozestan, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Behzad sharif Makhmalzadeh

Street address

Vice chancellor for research, Ahvaz Jundishapour University of Medical Science, Golestan Ave, Khouzestan, Ahvaz

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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, Ahvaz Jundishapour
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Elmira yousefi

Position

Ms.c student of Nutrition Science

Other areas of specialty/work**Street address**

Dept of Nutrition, School of Paramedical, Ahvaz
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Full name of responsible person

Majid Mohammad Shahi

Position

Assistant professor

Other areas of specialty/work**Street address**

Dept of Nutrition, School of Paramedical, Ahvaz

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty