Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 persent 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 alphalinolenic 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

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Iran (Islamic Republic of)

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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
Befor intervention and two months after intervention
Method of measurement
ELISA Test

6

Description
Nitric Oxide
Timepoint
Befor intervention and two months after intervention
Method of measurement
ELISA Test

7

Description
Malondialdehyde
Timepoint
Befor intervention and two months after intervention
Method of measurement
ELISA Test

8

Description
High-density lipoprotein
Timepoint
Befor intervention and two months after intervention
Method of measurement
spectrophotometer Test

9

Description
Low-density lipoprotein
Timepoint
Befor intervention and two months after intervention
Method of measurement
spectrophotometer Test

10

Description
Triglycerides
Timepoint
Befor intervention and two months after intervention
Method of measurement
spectrophotometer Test

11

Description
Total cholesterol
Timepoint
Befor 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
Ahwaz

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