Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Astaxanthin intake on expression of miR-146a and miR-126 in plasma, oxidative stress and inflammation markers and glycemic profile, compared with placebo in patients with type 2 diabetes mellitus

Protocol summary

Summary

Objectives: The aim of this study is to determine the effects of Astaxanthin on some of the oxidative stress and inflammation markers, and blood sugar in patients with type 2 diabetes. Design: This is a triple-blind clinical trial including 48 patients with type 2 diabetes, who are referred to endocrinology clinic at Golestan hospital and have been receiving oral treatments for glycemic control more than six months. Subjects will be followed for a period of 8 weeks on a voluntary manner. Blinding will be done for subjects and researchers and data monitoring committee. Setting, conduct and participants : 48 patients with type 2 diabetes, age 30 to 60 years, BMI 19 to 35 kg per square meter, and 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 24 patients)will receive 8 milligrams of Astaxanthin tablet daily and the control group (included 24 patients) will use placebo tablets with the same color and shape compared with Astaxanthin tablets for 8 weeks. To assess the dietary factors affecting the inflammatory condition in diabetic 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 food questionnaire will be completed by the patients and will be evaluated .Finally data will be analyzed by N4 software. Patients' weight will be measured with minimal clothes, without shoes by a digital scale. Main outcome measures: The main variables (consist of body fat percentage; blood pressure and biochemical parameters) will be measured and reported at the beginning and the end of the study, and will be compared with each other with appropriate statistical tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081623645N1**
Registration date: **2015-12-13, 1394/09/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-13, 1394/09/22

Registrant information

Name

Nafiseh Shokri Mashhadi

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Country

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+98 616135715751

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-10-07, 1394/07/15

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Astaxanthin intake on expression of miR-146a and miR-126 in plasma, oxidative stress and inflammation markers and glycemic profile, compared with placebo in patients with type 2 diabetes mellitus

Public title
Effect of astaxanthin intake in patients affected by type 2 diabetes mellitus

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Willingness to participate in the study, age range between 30-60 years old, Body Mass Index range between 19 and 35 kg per m2, HbA1C more than seven, not to be affected by renal, liver, lung and autoimmune disease, normal thyroid status, patients who have received standard oral treatments for at least six months. Exclusion criteria:Failure to follow the study

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple 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
Khuozestan, Ahvaz, Ahvaz Jundishapur University of Medical Sciences, Ethics Committee

City
Ahvaz

Postal code
61357-15794

Approval date
2015-07-25, 1394/05/03

Ethics committee reference number
1394.243.IRAJUMAS.REC

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E11,E12

ICD-10 code description
Non-insulin-dependent diabetes mellitus, Malnutrition-related diabetes mellitus

Primary outcomes

1

Description
FBS

Timepoint
at first and two months after intervention

Method of measurement
glucose enzymatic kit

2

Description
Fructosamine

Timepoint
at first and two months after intervention

Method of measurement
ELISA

3

Description
HDL

Timepoint
at first and two months after intervention

Method of measurement
spectrophotometer

4

Description
LDL

Timepoint
at first and two months after intervention

Method of measurement
spectrophotometer

5

Description
TG

Timepoint
at first and two months after intervention

Method of measurement

spectrophotometer

6

Description
IL6
Timepoint
at first and two months after intervention
Method of measurement
Elisa kit

7

Description
Adiponectin
Timepoint
at first and 2 months after intervention
Method of measurement
ELISA

8

Description
MDA
Timepoint
at first and two months after intervention
Method of measurement
TBARS

Secondary outcomes

empty

Intervention groups

1

Description
Using of food supplement contain 8 mg of Astaxanthin daily orally for 8-weeks Made in USA
Category
Treatment - Drugs

2

Description
Use of a placebo pill containing starch and manufacture by Faculty of Pharmacy of Ahvaz Jundishapur University of Medical Sciences for 8-weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital Endocrinology Clinic
Full name of responsible person
Mehrnoush Zakerkish
Street address
Endocrinology Clinic, Golestan Hospital, Golestan Ave,Ahvaz, Khuozestan
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
Mostafa Feghhi
Street address
Vice chancellor for research, Ahvaz Jundishapur University of Medical Science,Golestan Ave, Ahvaz,Khouzestan
City
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
Ahvaz Jundishapour University of Medical Sciences
Full name of responsible person
Nafiseh Shokri
Position
Phd Candidate of Nutrition Science
Other areas of specialty/work
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Person responsible for scientific inquiries

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Majid Mohammad Shahi

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Professor assistant

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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