

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 616135715751

##### Email address

shokri.n@ajums.ac.ir

##### 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 m<sup>2</sup>, 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**

Mehnoush 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 Jundishapur University of Medical Sciences

##### **Full name of responsible person**

Mostafa Fegghi

##### **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 Jundishapur 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 Jundishapur University of Medical Sciences

##### **Full name of responsible person**

Nafiseh Shokri

##### **Position**

Phd Candidate of Nutrition Science

##### **Other areas of specialty/work**

##### **Street address**

Dept of Nutrition, School of Paramedical, Ahvaz Jundishapur University of Medical Science,Golestan Ave, Ahvaz,Khouzestan

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Majid Mohammad Shahi

**Position**

Professor assistant

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

Phd Candidate of Nutrition Science

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**Web page address**

## 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*