

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Aug 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 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**  
Khuzestan, 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 Fegghi

#### Street address

Vice chancellor for research, Ahvaz Jundishapour 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

#### Street address

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

#### City

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#### Postal code

#### Phone

+98 61 3373 8330

#### Fax

#### Email

nafiseh.shokri@yahoo.com , shokri.n@ajums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Majid Mohammad Shahi

**Position**

Professor assistant

**Other areas of specialty/work**

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**Web page address**

## Person responsible for updating data

### 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**

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nafiseh.shokri@yahoo.com

**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*