

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### The effect of twelve weeks of high-intensity functional training with Astaxanthin supplementation on some inflammatory and antioxidant markers, adipokines, myokines, and hepatokines in men with obesity

#### Protocol summary

##### Study aim

The effect of twelve weeks of high-intensity functional training with Astaxanthin supplementation on some inflammatory markers in men with obesity

##### Design

Clinical trial with control group, randomized, single center trial, Sample size 44 people.

##### Settings and conduct

Twelve weeks of high -intensity functional exercises are accompanied by Astaxanthin supplement for 44 obese men (4 groups of 11). Tehran health centers

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: No addiction to drugs and alcohol; Not having a history of regular sports activity for at least 6 months; No history disease; Not having any injury or physical problem; Body mass index (BMI)=30; Waist-to-height ratio (WtHR)>0.5 Exclusion Criteria: Any psychological disorder to the individual's own report; Use of psychiatric drugs before conducting study

##### Intervention groups

Intervention group1: In this group, according to the protocol, they will perform a high-intensity functional training program (HIFT) in 36 sessions of 60 minutes, in which CrossFit is used. Intervention group2: In this group, according to the protocol, they will perform a high-intensity functional training program (HIFT) in 36 sessions of 60 minutes, in which CrossFit is used. and they will take 20 mg of astaxanthin capsules (Seongnam, South Korea) daily with breakfast for 12 weeks. Intervention group3: In this group, according to the protocol, they will only do their daily exercises for 12 weeks and will be prohibited from participating in regular activities. and they will take 20 mg of astaxanthin capsules (Seongnam, South Korea) daily with breakfast for 12 weeks. Control group: In this group, only do their daily exercises for 12 weeks and will be prohibited from participating in regular activities. They will receive 20 mg

of raw corn starch capsules (placebo) daily with breakfast.

##### Main outcome variables

Adipokines, Myokines, Hepatokines

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151228025732N76**

Registration date: **2023-03-10, 1401/12/19**

Registration timing: **prospective**

Last update: **2023-03-10, 1401/12/19**

Update count: **0**

##### Registration date

2023-03-10, 1401/12/19

##### Registrant information

##### Name

Alireza Emadi

##### Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3345 1336

##### Email address

are20935@semums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2023-03-16, 1401/12/25

##### Expected recruitment end date

2023-06-15, 1402/03/25

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of twelve weeks of high-intensity functional training with Astaxanthin supplementation on some inflammatory and antioxidant markers, adipokines, myokines, and hepatokines in men with obesity

**Public title**

The effect of twelve weeks of high-intensity functional training with Astaxanthin supplementation on some inflammatory markers in men with obesity

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

No addiction to drugs and alcohol Not having a history of regular sports activity for at least 6 months No history of kidney, liver, cardiovascular disease and diabetes Not having any injury or physical problem Body mass index (BMI)=30 Waist-to-height ratio (WHtR)>0.5

**Exclusion criteria:**

Any psychological disorder to the individual's own report  
Use of psychiatric drugs before conducting study

**Age**From **23 years** old to **32 years** old**Gender**

Male

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **44****Randomization (investigator's opinion)**

Randomized

**Randomization description**

We will construct 6 blocks in AABB, BBAA, ABAB, BABA, ABBA, and BAAB using four blocks. We will assign 1 to 6 for each block. Then, using the random number table, based on the sample size, 11 units of 4 blocks will be selected so that we consider having 11 people in the group (A), 11 people in the group (B), 11 people in the group (C) and 11 people in the group (D). Therefore, we will do block randomization.

**Blinding (investigator's opinion)**

Not 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 Islamic Azad University,  
Damghan branch

**Street address**

Islamic Azad University, Damghan branch; above  
Saadi square; Damghan.

**City**

Damghan

**Province**

Semnan

**Postal code**

3671637849

**Approval date**

2022-12-24, 1401/10/03

**Ethics committee reference number**

IR.IAU.DAMGHAN.REC.1401.035

**Health conditions studied****1****Description of health condition studied**

Obesity and overweight

**ICD-10 code**

E66

**ICD-10 code description**

Overweight and obesity

**Primary outcomes****1****Description**

Adipokines

**Timepoint**

The first fasting blood sample 48 hours before and the  
second blood sample 48 hours after the twelve-week  
training period from the right arm

**Method of measurement**

They will be measured using laboratory kits and ELISA  
devices

**2****Description**

Myokines

**Timepoint**

The first fasting blood sample 48 hours before and the  
second blood sample 48 hours after the twelve-week  
training period from the right arm

**Method of measurement**

They will be measured using laboratory kits and ELISA  
devices

**3****Description**

Hepatokines

**Timepoint**  
The first fasting blood sample 48 hours before and the second blood sample 48 hours after the twelve-week training period from the right arm

**Method of measurement**  
They will be measured using laboratory kits and ELISA devices

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group1: In this group, according to the protocol, they will perform a high-intensity functional training program (HIFT) in 36 sessions of 60 minutes, in which CrossFit is used. Daily exercise program: including aerobic exercise (running, jumping rope); Movements using body weight (barfix, squat) and weight lifting (front squat) are constantly changed using the CrossFit training pattern. The duration of each of the three workout programs is 20 minutes.

#### Category

Treatment - Other

### 2

#### Description

Intervention group2: In this group, according to the protocol, they will perform a high-intensity functional training program (HIFT) in 36 sessions of 60 minutes, in which CrossFit is used. and they will take 20 mg of astaxanthin capsules (Seongnam, South Korea) daily with breakfast for 12 weeks.

#### Category

Treatment - Other

### 3

#### Description

Intervention group3: In this group, according to the protocol, they will only do their daily exercises for 12 weeks and will be prohibited from participating in regular activities. and they will take 20 mg of astaxanthin capsules (Seongnam, South Korea) daily with breakfast for 12 weeks.

#### Category

Treatment - Other

### 4

#### Description

Control group: In this group, no treatment will be given and they will only do their daily exercises for 12 weeks and will be prohibited from participating in regular activities. They will receive 20 mg of raw corn starch capsules (placebo) daily with breakfast. It is only for comparison with intervention groups.

## Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tehran health centers

##### Full name of responsible person

Ayoub Saeidi

##### Street address

Payandeh St., Iranmehr St., Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1714956543

##### Phone

+98 21 3379 1873

##### Email

are20935@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Nemat Allah Nemati

##### Street address

Islamic Azad University, Damghan branch; above Saadi square; Damghan.

##### City

Damghan

##### Province

Semnan

##### Postal code

3671637849

##### Phone

+98 23 3522 5045

##### Email

info@damghaniau.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Islamic Azad University

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

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

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Ayoub Saeidi  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physical education and sports sciences - sports physiology  
**Street address**  
Islamic Azad University, Damghan branch; above Saadi square; Damghan.  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Ayoub Saeidi  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
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Ayoub Saeidi  
**Position**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available