

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 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 (WHR)>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)

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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 (WtR)>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

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Payandeh St., Iranmehr St., Tehran

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1714956543

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Nemat Allah Nemati

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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
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Person responsible for updating data

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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