

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effect of high-intensity interval training and beta-alanine supplementation on the basal levels and acute exercise response of oxidative-inflammatory markers in overweight/obese men

#### Protocol summary

##### Study aim

This study aimed to investigate the synergistic effects of six weeks of high-intensity interval training and beta-alanine supplementation as a limiting precursor of intramuscular carnosine synthesis on basal levels and acute exercise response of oxidative-inflammatory markers in overweight and obese men.

##### Design

The clinical trial includes a double-blind control group and three other groups, randomized on 28 overweight and obese men aged 18 to 35 years. Also, the tools available on the GraphPad website will be used for randomization.

##### Settings and conduct

The study will be conducted in the Sports Physiology Laboratory of Shahid Beheshti University. The subjects will be invited to study with an announcement. After early tests conduction, the subjects will be divided into four groups randomly and double-blindly. after that, the main intervention will be done for six-week, and the post-test will be done.

##### Participants/Inclusion and exclusion criteria

Include: Men; Inactive; Age 18 to 35 years; Body mass index 25 to 35 kg per square meter; Body fat percent 25 to 35%; Exclude: smoking; Alcohol consumption; Blood Glucose above 110 mg/dL; Hematocrit below 35%; Hemoglobin below 13 g/dL; Leukocyte more than 11,000 per Micro liter; Having an underlying disease

##### Intervention groups

1- Training and beta-alanine group: Six weeks of high-intensity interval training, along with a daily intake of 6.4 grams of beta-alanine; 2- Training and placebo group: Six weeks of high-intensity interval training, along with a daily intake of 6.4 grams of dextrose (placebo); 3- beta-alanine group: daily intake of 6.4 grams of beta-alanine without any training; 4- Control group: daily intake of 6.4 grams of dextrose (placebo) without any training.

#### Main outcome variables

Serum tumor necrosis factor alpha; Serum high-sensitivity C-reactive protein; Serum interleukin 10; Serum Malondialdehyde; Serum total antioxidant capacity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220828055811N1**  
Registration date: **2022-10-10, 1401/07/18**  
Registration timing: **prospective**

Last update: **2022-10-10, 1401/07/18**

Update count: **0**

##### Registration date

2022-10-10, 1401/07/18

##### Registrant information

##### Name

Mohamad Saber Ebrahimi Zarandi

##### Name of organization / entity

Shahid Beheshti University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2990 5825

##### Email address

m.ebrahimizarandi@mail.sbu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-22, 1401/07/30

##### Expected recruitment end date

2023-01-20, 1401/10/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of high-intensity interval training and beta-alanine supplementation on the basal levels and acute exercise response of oxidative-inflammatory markers in overweight/obese men

**Public title**

Effect of high-intensity interval training on obesity

**Purpose**

Basic science

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Men Body mass index from 25 to 35 kilogram per square meter All persons with at least 25 percent body fat Inactive Age 18 to 35 years

**Exclusion criteria:**

Smoking Having an underlying disease Blood Glucose above 110 mg per liter; Hematocrit below 35% Hemoglobin below 13 g/dl WBC count more than 11,000 per microliter

**Age**

From **18 years** old to **35 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **28**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Subjects will be divided individually into four groups by the simple randomization method and with the help of the randomization tool available on the GraphPad website ([www.graphpad.com](http://www.graphpad.com)).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

All subjects participating in the study will receive identical capsules, which will have the same appearance. Dextrose will be used as the placebo due to its identical appearance to beta-alanine. Subjects will not be informed of the type of supplement they are taking until the end of the study. All the capsules will be prepared by someone outside the study and will be given to the subjects by the same person, and the researchers will not know the type of capsule consumed by the subjects.

Also, the grouping and randomization of subjects will be done by someone outside the study. The main researcher and the data evaluator will not know about the grouping of subjects until the end of the study. The analyzer will also analyze the data without knowing which data belongs to each group. Then it will be clear which data belongs to each group.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Shahid Beheshti University

**Street address**

Shahid Beheshti University, Shahid Shahriari Square, Evin, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Approval date**

2022-05-14, 1401/02/24

**Ethics committee reference number**

IR.SBU.REC.1401.045

**Health conditions studied**

**1**

**Description of health condition studied**

Obesity

**ICD-10 code**

E66

**ICD-10 code description**

Overweight and obesity

**Primary outcomes**

**1**

**Description**

Serum tumor necrosis factor alpha (TNF $\alpha$ )

**Timepoint**

At the beginning of the study, six weeks after the start of the supplement and exercises and 30 minutes after the end of the last training session.

**Method of measurement**

Using ELISA method and kit made in Germany (LDN company).

## 2

### **Description**

Serum high-sensitivity C-reactive protein (hs-CRP)

### **Timepoint**

At the beginning of the study, six weeks after the start of the supplement and exercises and 30 minutes after the end of the last training session.

### **Method of measurement**

Using ELISA method and kit made in Germany (LDN company).

## 3

### **Description**

Serum interleukin 10

### **Timepoint**

At the beginning of the study, six weeks after the start of the supplement and exercises and 30 minutes after the end of the last training session.

### **Method of measurement**

Using ELISA method and kit made in Germany (LDN company).

## 4

### **Description**

Serum Malondialdehyde (MDA)

### **Timepoint**

At the beginning of the study, six weeks after the start of the supplement and exercises and 30 minutes after the end of the last training session.

### **Method of measurement**

Using Fluorometric method and kit made in Iran (KPG company).

## 5

### **Description**

Serum total antioxidant capacity

### **Timepoint**

At the beginning of the study, six weeks after the start of the supplement and exercises and 30 minutes after the end of the last training session.

### **Method of measurement**

Using Fluorometric method and kit made in Iran (KPG company).

## **Secondary outcomes**

## 1

### **Description**

Body Composition

### **Timepoint**

At the beginning of the study and six weeks after the start of the supplement and training.

### **Method of measurement**

Using inbody 770 machine

## 2

### **Description**

High Density Lipoprotein (HDL)

### **Timepoint**

At the beginning of the study and six weeks after the start of the supplement and training.

### **Method of measurement**

Using Hitachi 717 machine and kit made in Iran.

## 3

### **Description**

Low Density Lipoprotein (LDL)

### **Timepoint**

At the beginning of the study and six weeks after the start of the supplement and training.

### **Method of measurement**

Using Hitachi 717 machine and kit made in Iran.

## 4

### **Description**

Triglyceride (TG)

### **Timepoint**

At the beginning of the study and six weeks after the start of the supplement and training.

### **Method of measurement**

Using Hitachi 717 machine and kit made in Iran.

## 5

### **Description**

Cholesterol

### **Timepoint**

At the beginning of the study and six weeks after the start of the supplement and training.

### **Method of measurement**

Using Hitachi 717 machine and kit made in Iran.

## **Intervention groups**

## 1

### **Description**

First intervention group: Consumption of beta-alanine supplement from My Protein company for six weeks in the amount of 6.4 grams daily in the form of 8 capsules of 0.8 grams (two capsules in each main meal) and performing three sessions of high-intensity interval training (10 one-minute intervals with 80% of maximum aerobic power and one-minute recovery with 20% of maximum aerobic power between intervals).

### **Category**

Prevention

## 2

### **Description**

Second intervention group: Consumption of beta-alanine supplement from My Protein company for six weeks in the amount of 6.4 grams daily in the form of 8 capsules of 0.8 grams (two capsules in each main meal).

### **Category**

Prevention

### 3

#### Description

Third intervention group: Consumption of placebo (Dextrose) for six weeks in the amount of 6.4 grams daily in the form of 8 capsules of 0.8 grams (two capsules in each main meal) and performing three sessions of high-intensity interval training (10 one-minute intervals with 80% of maximum aerobic power and one-minute recovery with 20% of maximum aerobic power between intervals).

#### Category

Prevention

### 4

#### Description

Control group: Consumption of placebo (Dextrose) for six weeks in the amount of 6.4 grams daily in the form of 8 capsules of 0.8 grams (two capsules in each main meal)

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

University of Shahid Beheshti

##### Full name of responsible person

Mohamad Saber Ebrahimi Zarandi

##### Street address

Shahid Shahriari Square, Evin, Tehran

##### City

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##### Province

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##### Postal code

1983969411

##### Phone

+98 21 2990 5821

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##### Email

sportscience@sbu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

The University of Shahid Beheshti

##### Full name of responsible person

Babak Shokri

##### Street address

Shahid Shahriari Square, Evin, Tehran

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##### Postal code

1983969411

##### Phone

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##### Email

b-shokri@sbu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

The University of Shahid Beheshti

#### Proportion provided by this source

20

#### 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

The University of Shahid Beheshti

##### Full name of responsible person

Mohamad Saber Ebrahimi Zarandi

##### Position

Master of science student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Exercise Physiology

##### Street address

Boys' dormitory of Shahid Beheshti University, Daneshjoo Blvd., Shahid Shahriari Square, Evin, Tehran

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##### Postal code

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

The University of Shahid Beheshti

##### Full name of responsible person

Mohamad Saber Ebrahimi Zarandi

##### Position

Master of science student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Exercise Physiology

**Street address**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

The University of Shahid Beheshti

**Full name of responsible person**

Afshar Jafari

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Exercise biochemistry, exercise physiology, Molecular  
exercise physiology

**Street address**

No. 1, Yas Building, South Nobahar, end of Aqdasiyeh,  
Azgol, Tehran

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Only primary and secondary data will be presented as an  
article.

**When the data will become available and for how  
long**

The access period starts six months after the results are  
published.

**To whom data/document is available**

The present research data will be available to  
researchers in academic and scientific institutions in the  
form of general statistical data, or people who are also  
engaged in the industry can apply for it after the  
publication of the article.

**Under which criteria data/document could be used**

The present study's data will be made available to others  
in the form of general statistics (without reference to the  
raw data of the subjects) with the researchers'  
permission.

**From where data/document is obtainable**

Applicants can contact me by phone, WhatsApp, or  
email.

**What processes are involved for a request to access  
data/document**

After contacting me and reviewing the request, it will be  
reviewed if necessary.

**Comments**