Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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 scienece

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).

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 (TNFα)

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of Shahid Beheshti

Full name of responsible person
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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
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

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

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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

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Other areas of specialty/work

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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

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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