

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The Effects of L-Carnitine Supplementation during Endurance Training on Some Serum Angiogenesis Indices and Blood Pressure Changes in Obese Young Women

#### Protocol summary

##### Study aim

The purpose of this research is to investigate the effects of l-carnitine supplementation during endurance training on some serum angiogenesis indices and blood pressure changes in obese young women.

##### Design

A clinical trial with a control group, parallel, double-blind, randomized, with a predicted sample size of 40 and phase 3 trial

##### Settings and conduct

This study will be conducted on obese women living in the city of Marivan. The duration of the research is 8 weeks and the participants are divided into four groups randomly. The interventional factor including endurance and l-carnitine supplementation is considered for this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: being 20–30 years old, being female, having a body mass index over than 30 kg/m<sup>2</sup>; exclusion criteria: smoking, taken the drug or supplement, having a kind of specific disease and having regular exercise.

##### Intervention groups

Intervention group 1: Implementation of endurance exercise with consuming 3 grams of l-carnitine supplementation for 8 weeks Intervention group 2: Implementation of endurance exercise with consuming 3 grams of placebo (maltodextrin) for 8 weeks Intervention group 3: Consumption of 3 grams of l-carnitine supplementation alone for 8 weeks Intervention group 4: Control group (they will not receive any intervention)

##### Main outcome variables

Endothelial growth factor; Nitric oxide; Endostatin; Interleukin-6; Blood pressure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150412021719N2**

Registration date: **2019-08-16, 1398/05/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-08-16, 1398/05/25**

Update count: **0**

##### Registration date

2019-08-16, 1398/05/25

##### Registrant information

##### Name

Mehdi Hakimi

##### Name of organization / entity

University of Mohaghegh Ardabili

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3351 2081

##### Email address

mehdihakimi@uma.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-23, 1398/05/01

##### Expected recruitment end date

2019-08-22, 1398/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effects of L-Carnitine Supplementation during Endurance Training on Some Serum Angiogenesis Indices and Blood Pressure Changes in Obese Young Women

#### Public title

The effect of exercise training with ingested of l-carnitine on angiogenesis

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Participants in the current study must be non-athlete  
Participants in the current study must be at the age range of 20-30 years  
Participants in the current study must be woman  
Participants in the current study must be obese

##### Exclusion criteria:

People who consuming tobacco are not allowed to participate in this study  
People who taking the drug or nutrition supplement are not allowed to participate in this study  
People who having a kind of special disease are not allowed to participate in this study

#### Age

From **20 years** old to **30 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

- Participant
- Investigator
- Outcome assessor

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Simple random, the chance of all subjects for divided into two groups of supplement and placebo were similar

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The participants and researchers in this study will be blind to the use of supplementation or placebo

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Kurdistan University of Medical

Sciences

#### Street address

Kurdistan University of Medical Sciences, Pasdaran Street

#### City

Sanandaj

#### Province

Kurdistan

#### Postal code

6617713446

#### Approval date

2019-07-15, 1398/04/24

#### Ethics committee reference number

IR.MUK.REC.1398.079

### Health conditions studied

#### 1

##### Description of health condition studied

Obesity

##### ICD-10 code

E66.0

##### ICD-10 code description

Obesity due to excess calories

### Primary outcomes

#### 1

##### Description

Endothelial growth factor

##### Timepoint

Basal state and after 8 week

##### Method of measurement

Based on nanogram per liter with ELISA method

#### 2

##### Description

Nitric oxide

##### Timepoint

Basal state and after 8 week

##### Method of measurement

Based on micromole per liter with ELISA method

#### 3

##### Description

Interleukin 6

##### Timepoint

Basal state and after 8 week

##### Method of measurement

Based on picogram per milliliter with ELISA method

#### 4

##### Description

Endostatin

##### Timepoint

Basal state and after 8 week

##### Method of measurement

Based on nanogram per liter with ELISA method

## 5

### **Description**

Blood pressure

### **Timepoint**

Basal state and after 8 week

### **Method of measurement**

Based on millimeter mercury with digital blood pressure monitor

## 6

### **Description**

Interleukin 4

### **Timepoint**

Basal state and after 8 week

### **Method of measurement**

Based on nanogram per liter with ELISA method

## 7

### **Description**

Interleukin 8

### **Timepoint**

Basal state and after 8 week

### **Method of measurement**

Based on nanogram per liter with ELISA method

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

First intervention group: The subjects of endurance exercise with l- carnitine group will participate in 8 weeks of endurance training with the ingestion of l- carnitine supplement. Blood samples will take in basal state and after 8 weeks.

#### **Category**

Prevention

### 2

#### **Description**

second intervention group: The subjects of endurance exercise with placebo group will participate in 8 weeks of endurance training with the ingestion of placebo. Blood samples will take in basal state and after 8 weeks.

#### **Category**

Prevention

### 3

#### **Description**

Third intervention group: The subjects of l- carnitine group will participate in 8 weeks of ingestion of l- carnitine supplement. Blood samples will take in basal

state and after 8 weeks.

#### **Category**

Prevention

### 4

#### **Description**

Control group: The subjects of control group (There will be no intervention). Blood samples will take in basal state and after 8 weeks.

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Sanandaj Branch, Islamic Azad University

##### **Full name of responsible person**

Maryam Ali-Mohammadi

##### **Street address**

Islamic Azad University, Pasdaran Blvd, Sanandaj

##### **City**

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6616935391

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+98 87 3328 8661

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Maryam.alimohamadi66@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University

##### **Full name of responsible person**

Dr. Abdollah Refaei

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Islamic Azad University, Pasdaran Blvd, Sanandaj

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refaei@iausdj.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**  
Maryam Ali- Mohammadi  
**Position**  
Phd Student  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Sport Medicine  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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Kamal Aziz-Beigi  
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Associate professor  
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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
Mehdi Hakimi  
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Mehdihakimi@uma.ac.ir

## 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

All relevant data and tests will be published without mentioning the name.

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

Data will be available after the publication of the articles.

### To whom data/document is available

All researchers can access the data.

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

The possibility of using this data to analyze and write an article will not be given to individuals.

### From where data/document is obtainable

By emailing the accountability officer, they can access the documentation.

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

After receiving the email, the file will be sent to the

researchers.

**Comments**