

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/m²; 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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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
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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

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