

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Effect of L-carnitine supplementation and moderate aerobic training on some serum indices of oxidative stress, inflammation and insulin resistance in obese women

#### Protocol summary

##### Summary

The objective of this randomized double-blind placebo controlled trial is to investigate the effect of L-carnitine supplementation and moderate aerobic training on the metabolic outcomes of obesity in obese women. Subjects with obesity will be recruited from exercise clubs in Tabriz including 44 individuals. Subjects will be randomly assigned to receive either 250mg L-carnitine oral tablet or corn starch placebo tablets for 60 days. In training groups subjects will participate in moderate aerobic training 3 times a week (24 sessions) for 8 weeks. Anthropometric measurements (weight, height, waist and hip circumference, waist to hip ratio, body fat percentage %), VO<sub>2</sub> max, biochemical parameters (lipid profile including total cholesterol, LDL and HDL cholesterol and triglyceride concentrations, fasting glucose and insulin level, IL-6, IL-10, hs-CRP, TAC, MDA levels), concentrations of serum L-carnitine and dietary data obtained from 3-day food records will be measured before and after treatment and compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138901193664N1**  
Registration date: **2010-07-04, 1389/04/13**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-07-04, 1389/04/13

##### Registrant information

Name

Maryam Rafraf

##### Name of organization / entity

Tabriz University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7580

##### Email address

rafrafm@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for Research, Tabriz University Of Medical Sciences

##### Expected recruitment start date

2009-09-23, 1388/07/01

##### Expected recruitment end date

2009-11-22, 1388/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of L-carnitine supplementation and moderate aerobic training on some serum indices of oxidative stress, inflammation and insulin resistance in obese women

##### Public title

L-carnitine supplementation and moderate aerobic training in obese women

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: women with BMI  $\geq$  30, %BF  $\geq$  30, age

20-50 years old. Exclusion criteria: any disease that influence metabolic parameters in this trial (liver, cardiovascular, kidney or gastrointestinal diseases, hypo/hyper thyroidism, orthopedic problems, Romatoid arthritis, diabetes, hypertension), pregnancy, receiving any vitamin or mineral supplements, people who have usual aerobic training program (more than 3 times a week, 2 hours every time), any special diet.

#### **Age**

From **20 years** old to **50 years** old

#### **Gender**

Female

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **44**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Factorial

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Tabriz University Of Medical Sciences

###### **Street address**

Attare Neishaboori Avenue, Golgasht Street

###### **City**

Tabriz

###### **Postal code**

##### **Approval date**

2009-10-11, 1388/07/19

##### **Ethics committee reference number**

5/4/5478

### **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**

L-carnitine serum value

##### **Timepoint**

Baseline and at the end of intervention

##### **Method of measurement**

kit & spectrophotometry

### **Secondary outcomes**

#### **1**

##### **Description**

Fasting serum insulin values & Insulin resistance index

##### **Timepoint**

Baseline and at the end of intervention

##### **Method of measurement**

chemiluminescence & HOMA formula

#### **2**

##### **Description**

Fasting serum glucose values

##### **Timepoint**

Baseline and at the end of intervention

##### **Method of measurement**

Enzymatic method, automatic analyzer

#### **3**

##### **Description**

Fasting serum lipid profile (LDL,HDL,total cholesterol,TG)

##### **Timepoint**

Baseline and at the end of intervention

##### **Method of measurement**

Enzymatic method, with special kits for assessing TG, HDL, total cholesterol and Friedewald equation for assessing LDL cholesterol

#### **4**

##### **Description**

Serum inflammatory values (IL-6 ,IL-10, hs-CRP)

##### **Timepoint**

Baseline and at the end of intervention

##### **Method of measurement**

hs-CRP assess with immunoturbidometric method and IL-6& IL-10 with elayza method

#### **5**

##### **Description**

serum indices of oxidative stress (TAC,MDA)

##### **Timepoint**

Baseline and at the end of intervention

##### **Method of measurement**

TAC with special kits, MDA with chemical-calorimetric & reaction with tiobarbitoric acid

## 6

### **Description**

Antropometric indicators (weight, height, BMI, Waist circumference, hip circumference, Waist to Hip Ratio)

### **Timepoint**

Baseline and at the end of intervention

### **Method of measurement**

physical exam

## 7

### **Description**

Measurement of Peak Aerobic Capacity - VO2max

### **Timepoint**

Baseline and at the end of intervention

### **Method of measurement**

With Rockport Walking Test

## 8

### **Description**

Body Fat %

### **Timepoint**

Baseline and at the end of intervention

### **Method of measurement**

ACSM formula and measurement of skin fold thickness according to three site measurements

## **Intervention groups**

### 1

#### **Description**

Only Placebo, 8 tablets a day for 8 weeks (insoluble starch)

#### **Category**

Placebo

### 2

#### **Description**

moderate aerobic training, 3 times a week (24 sessions, every session 45 minutes) for 8 week plus Placebo

#### **Category**

Lifestyle

### 3

#### **Description**

L-carnitine, 8 tablets daily for 8 weeks (each tablet contains 250 mg of L-carnitine) without aerobic training

#### **Category**

Treatment - Drugs

### 4

#### **Description**

L-carnitine, 8 tablets daily for 8 weeks (each tablet contains 250 mg of L-carnitine) plus moderate aerobic training, 3 times a week (24 sessions, every session 45 minutes) for 8 week

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Exercise clubs in Tabriz

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

Mina Karimi

##### **Street address**

##### **City**

Tabriz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Vice-chancellor for research, Tabriz Nutrition

Research Center, Tabriz University of Medical Science

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

Maryam Rafraf

##### **Street address**

Health and Nutrition school, Attare Neishabouri avenue, Golgasht street

##### **City**

Tabriz

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Vice-chancellor for research, Tabriz Nutrition Research Center, Tabriz University of Medical Science

#### **Proportion provided by this source**

100

#### **Public or private sector**

*empty*

#### **Domestic or foreign origin**

*empty*

#### **Category of foreign source of funding**

*empty*

#### **Country of origin**

#### **Type of organization providing the funding**

*empty*

## **Person responsible for general inquiries**

#### **Contact**

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

Tabriz University Of Medical Sciences

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

Mina Karimi

##### **Position**

MS student in Nutrition

##### **Other areas of specialty/work**

##### **Street address**

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**Other areas of specialty/work**

**Street address**

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**Phone**

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**Email**

**Web page address**

**Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*