Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of L-carnitine supplementation and modrate 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 modrate 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 be 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 2 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)

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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 modrate 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 ≥ 30, %BF≥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 artritis, 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
chemiluminescance & 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 srum 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 cholestrol and Friedewald equation for assessing LDL cholestrol

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 immunotorbidometric method andIL-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
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MS student in Nutrition
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Person responsible for updating data

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Full name of responsible person
Mina Karimi
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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