

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effect of L-carnitine supplementation on resting metabolism rate and body composition in obese women, Double blinded control trial

Protocol summary

Summary

Obesity, a serious risk factor for chronic diseases, especially among women, is an important worldwide public health problem. The aim of this study was to evaluate the effects of L-carnitine supplementation on resting metabolism rate and body composition in obese women. In this clinical trial, 60 obese women with 10-15% weight reduction were randomly assigned to two groups (n=30 each) as follows: L-carnitine supplementation (2g/day), 2: placebo corn starch tablets(placebo and L Carnitin by Karen pharmaceutical company). All interventions had a 4 week period and subjects along with weight loss diet (500cal daily calorie restriction). Body mass index, body fat percentage, and serum fasting free L-carnitine, resting metabolism rate and blood test for determination of triglyceride and thyroid hormone levels of each subjects were measured before and after interventions. Analysis of covariance was used for comparing of variables means between groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042417408N1**

Registration date: **2016-04-25, 1395/02/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-25, 1395/02/06

Registrant information

Name

Sajad Salarkia

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2631 1329

Email address

s-salarkia@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tehran University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2014-10-22, 1393/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of L-carnitine supplementation on resting metabolism rate and body composition in obese women, Double blinded control trial

Public title

Effect of L-carnitine supplementation on resting metabolism rate and body composition in obese women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: obese women (BMI 30-35) who succeed to lose 10 to 15% of body weight in last 3-6 months under the supervision of qualified dietitian and proper diet and also have clear diet records and the specified file Exclusion criteria: Patients (cardiac, pulmonary, diabetes and thyroid disease), smokers or people with

specific physiological conditions such as pregnancy, lactation and menopause, People who are taking multivitamin supplements and athletes are excluded.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

No. 20, Hojat doost St, Keshavarz Blvd, School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Postal code

Approval date

2014-08-10, 1393/05/19

Ethics committee reference number

93/130/986/ص

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

BMI

Timepoint

beginning and end of study (4 weeks)

Method of measurement

weight persons with a scale and height with a gauge and then put the results in equation of BMI (weight/height x Height)

2

Description

Percent of body fat

Timepoint

Beginning and end of study (4 weeks)

Method of measurement

Body composition device

3

Description

Amount (kg) of body fat

Timepoint

Beginning and end of study (4 weeks)

Method of measurement

Weight persons with a scale and height with a gauge and then put the results in equation of BMI (weight/height x Height)

4

Description

Amount of lean body mass

Timepoint

Beginning and end of study (4 weeks)

Method of measurement

Body composition device

5

Description

Waist to hip ratio

Timepoint

Beginning and end of study (4 weeks)

Method of measurement

Measure waist and hip size with a gauge and then use (waist/hip)

6

Description

Weight

Timepoint

Beginning and end of study (4 weeks)

Method of measurement

Weight person with scale

Secondary outcomes

1

Description

Lipid profile

Timepoint

At the beginning and end of study

Method of measurement

Blood test

2

Description

Resting metabolism rate

Timepoint

At the beginning and end of study

Method of measurement

Indirect calorimetry

Intervention groups

1

Description

Intervention group: L - carnitine, 1 gram tablets, 2 times per day for 4 weeks

Category

Treatment - Drugs

2

Description

Placebo group: Maltodextrin, 1-gram tablets, 2 times per day for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Sajad Salarkia

Street address

North Karegar Street, Shariati Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Younesyan

Street address

No. 20, Hojat doost St, Keshavarz Blvd, School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Grant name

93-01-161-25555-116552

Grant code / Reference number

0

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

Yes

Title of funding source

Vice Chancellor for research of Tehran University of Medical Sciences

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

Tehran University of Medical Sciences

Full name of responsible person

Jalal Moludi

Position

Ph.D of Nutrition

Other areas of specialty/work

Street address

No. 20, Hojat doost St, Keshavarz Blvd, School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences, Tehran, Iran.

City

Tehran

Postal code

982188974463

Phone

+98 21 8897 4463

Fax

+98 21 8897 4463

Email

jmoludi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Seyedali Keshavarz

Position

Phd

Other areas of specialty/work**Street address**

No. 20, Hojat doost St, Keshavarz Blvd, School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences, Tehran, Iran.

City

Tehran

Postal code**Phone**

+98 21 8802 8281

Fax

+98 21 8897 4463

Email

S_akeshavarz@yahoo.com

Web page address

..

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Sajad Salarkia

Position

MSc of Nutrition

Other areas of specialty/work**Street address**

No. 20, Hojat doost St, Keshavarz Blvd, School of

Nutritional Sciences and Dietetics, Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Postal code

582852850

Phone

+98 21 8897 4463

Fax

+98 21 8897 4463

Email

sajad.salarkia@gmail.com

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