

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of the effect of L-carnitine supplementation on homocysteine, total antioxidant capacity, fasting blood glucose and lipid profile in patients with type 2 diabetes

Protocol summary

Summary

The aim of this study is evaluating the effect of L-carnitine supplementation on homocysteine, total antioxidant capacity, fasting blood glucose and lipid profile in patients with type 2 diabetes. 66 diabetic patients will be randomly and double blinded divide into two intervention and control groups. The intervention consisted of 2 groups: 1. Two 500 mg/day L-carnitine tablet and 2. Two 500 mg/day Placebo. Anthropometric indices, biochemical, general and medical information and food records for each person will be collected at the baseline and at the end of the study. Duration of intervention will be 3 months. Individuals with following conditions will be excluded: Patients with Kidney disease; Hypothyroid patients that they were not treated; People with blood pressure upper than 150/90 mm; Use of L-carnitine and B group vitamins during the last 3 months; Antioxidant supplementation use (vitamins A, A, D and E) within 1 month Past; Smoking and hookah; Liver and gastrointestinal diseases; Having a systematic infection or surgery history 3 or 6 months ago; History of heart attacks; Unstable angina or congestion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100936681N1**

Registration date: **2017-10-28, 1396/08/06**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-28, 1396/08/06

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-09-01, 1397/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of L-carnitine supplementation on homocysteine, total antioxidant capacity, fasting blood glucose and lipid profile in patients with type 2 diabetes

Public title

The Effect of L-Carnitine Supplementation on Type 2 Diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Body mass index between 25 and 35; People aged 30 to 60 years old; Diabetes mellitus patients and HbA1c hemoglobin less than 9 percent and

Exclusion criteria: Kidney disease; Hypothyroid patients who were not treated; People with blood pressure upper than 150/90 mm; Use of L-carnitine and B group vitamins during last 3 months; Antioxidant supplementation use (vitamins A, A, D and E) within 1 month Past; smoking ; liver and gastrointestinal diseases; having a systematic infection or surgery history 3 or 6 months ago; history of heart attacks, unstable angina or congestion.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

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

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Street address

Central Building of Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd, Iran

City

Yazd

Postal code

8915173160

Approval date

2017-08-06, 1396/05/15

Ethics committee reference number

IR.SSU.SPH.REC.1396.90

Health conditions studied

1

Description of health condition studied

type 2 diabetes mellitus

ICD-10 code

E-11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

serum homocysteine

Timepoint

Before the intervention and three months after the intervention begin

Method of measurement

ELISA

2

Description

Total antioxidant capacity(TAC)

Timepoint

Before the intervention and three months after the intervention begin

Method of measurement

ELISA

3

Description

Serum Total cholesterol

Timepoint

Before the intervention and three months after the intervention begin

Method of measurement

using Appropriate kits, by Alpha-Classic autoanalyzer

4

Description

Serum triglyceride level (TG)

Timepoint

Before the intervention and three months after the intervention begin

Method of measurement

using Appropriate kits, by Alpha-Classic autoanalyzer

5

Description

Serum high density lipoprotein cholesterol (HDL-C)

Timepoint

Before the intervention and three months after the intervention begin

Method of measurement

Using Appropriate kits, by Alpha-Classic autoanalyzer

6

Description

Serum fasting blood sugar(FBS)

Timepoint

Before the intervention and three months after the intervention begin

Method of measurement

using Appropriate kits, by Alpha-Classic autoanalyzer

7**Description**

Serum low Density Lipoprotein cholesterol (LDL-C)

Timepoint

Before the intervention and three months after the intervention begin

Method of measurement

Using Appropriate kits, by Alpha-Classic autoanalyzer

Secondary outcomes**1****Description**

visceral fat percent

Timepoint

Before the intervention and three months after the intervention begin

Method of measurement

by body Calibrated scale

2**Description**

Body fat percent

Timepoint

Before the intervention and three months after the intervention begin

Method of measurement

by body Calibrated scale

3**Description**

BMI

Timepoint

Before the intervention and three months after the intervention begin

Method of measurement

by body Calibrated scale

4**Description**

Weight

Timepoint

Before the intervention and three months after the intervention begin

Method of measurement

by body Calibrated scale

5**Description**

Muscle mass percent

Timepoint

Before the intervention and three months after the intervention begin

Method of measurement

by body Calibrated scale

6**Description**

evaluation of patients diet

Timepoint

Before the intervention and three months after the intervention begin

Method of measurement

Three-day food record

Intervention groups**1****Description**

L-carnitine, an oral supplement of 500 mg twice daily for 12 weeks in the intervention group

Category

Treatment - Drugs

2**Description**

placebo, 500 mg tablet twice a day for 12 weeks in the placebo group

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Diabetes Research Center, Shahid Sadoughi University of Medical Sciences

Full name of responsible person

dr rahmannian

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Department of Nutrition, Faculty of Public Health, Shahid Sadoughi University of Medical Sciences, Alem Square, Yazd, Iran.

City

Yazd

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

shahid sadoughi yazd University of Medical Sciences

Full name of responsible person

Dr hassan mozaafari-khosravi

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City

Yazd

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
shahid sadoughi yazd 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

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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