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

Nasir Talenezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 9100

Email address

n.talenezhad@ssu.ac.ir

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
evalution 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
Street address
Department of Nutrition, Faculty of Public Health, Shahid Sadughi University of Medical Sciences, Alem Square, Yazd, Iran.
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
shahid sadughi yazd University of Medical Sciences
Full name of responsible person
Dr hassan mozaffari-khosravi
Street address
Department of Nutrition, Faculty of Public Health, Shahid Sadughi University of Medical Sciences, Alem Square, Yazd, Iran.
City
Yazd

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
shahid sadughi 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
Name of organization / entity
Shahid Sadoughi University of Medical Sciences, Yazd, Iran
Full name of responsible person
Nasir talenezhad
Position
MSc student of Health Sciences in Nutrition
Other areas of specialty/work
Street address
Department of Nutrition, Faculty of Public Health, Shahid Sadughi University of Medical Sciences, Alem Square, Yazd, Iran.
City
Yazd
Postal code
8915173160
Phone
00
Fax
Email
n.talenezhad@ssu.ac.ir n.talenezhad@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Sadoughi University of Medical Sciences, Yazd, Iran
Full name of responsible person
Dr hassan mozaffari-khosravi
Position
PhD in Nutrition Sciences
Other areas of specialty/work
Street address
Department of Nutrition, Faculty of Public Health, Shahid Sadughi University of Medical Sciences, Alem Square, Yazd, Iran.
City
Yazd
Postal code
8915173160
Phone
+98 353538209143
Fax
Email
mozaffari.kh@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Department of nutrition, faculty of Health, Shahid Sadoughi University of Medical Sciences, Yazd, Ir
Full name of responsible person
Nasir talenezahd
Position
MSc student of Health Sciences in Nutrition
Other areas of specialty/work
Street address
Shahid Sadoughi University of Medical Sciences, Yazd, Iran.
City
Yazd
Postal code
Phone
00
Fax
Email
n.talenezhad@ssu.ac.ir n.talenezhad@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