Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of L - carnitine on selected parameters of oxidative stress in patients with Hyperlipidemia

Protocol summary

Summary

(1) Objectives: The aim of this study is to investigate the effect of L-carnitine on selected parameters of oxidative stress in patients with Hyperlipidemia. (2) Design: This is a double-blind randomized placebo-controlled study. (3) Setting and conduct: 60 persons who referred to Baqiyatallah clinic(s) will be divided to equal groups, including 30 intervention (supplementation with L - carnitine) and 30 control (placebo) groups. After 14 hours of fasting, the blood samples of two groups will be measured. (4) Participants including major eligibility criteria: Inclusion criteria: Incidence of Hyperlipidemia and age range between 18-65 years; Both groups of males and females; Patients do not use Hypolipidemia drugs in 2 month ago. Exclusion criteria: Hypothyroidism disease; Acute Coronary Disease; Renal disease; Pregnancy; Usage of drugs and alcohol; Inflammatory disease; Chronic Liver Disease (Cirrhosis, Hepatitis, etc.); Anti-seizure drugs; Consumption of antioxidant supplements. (5) Intervention: The L - carnitine tablets will be administered in 2 g/day for the intervention group, and the same dose (2g/day) of placebo for control group in 8 week. During the study, subjects will be advised not to alter their regular diet and level of physical activity. At the end of this study, the parameters of two groups will be measured. (6) main outcome measures (variables): Total antioxidant capacity (TAC), Malondialdehyde (MDA) and the levels of reduced Glutathione (GSH).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014011416214N1**
Registration date: **2014-03-09, 1392/12/18**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2014-03-09, 1392/12/18

Registrant information

Name
Hesam Kazemzad
Name of organization / entity
Baqiyatallah University of Medical Sciences
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Iran (Islamic Republic of)
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+98 21 8804 0153
Email address
abbaszade@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Baqiyatallah University of Medical Sciences

Expected recruitment start date

2014-02-04, 1392/11/15

Expected recruitment end date

2014-06-05, 1393/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of L - carnitine on selected parameters of oxidative stress in patients with Hyperlipidemia

Public title

Effect of L - carnitine on oxidative stress markers in patients with Hyperlipidemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Incidence of Hyperlipidemia with Cholesterol levels ≥ 200 mg /dL or Triglycerides levels ≥ 200 mg /dL) or LDL ≥ 130; Age range between 18 and 65 years; Both groups of males and females; Patients do not use Hypolipidemia drugs in 2 month ago. Exclusion criteria: Hypothyroidism disease; Acute Coronary Disease; Renal disease; Pregnancy; Usage of drugs and alcohol; Inflammatory disease; Chronic Liver Disease (Cirrhosis, Hepatitis, etc.); Anti-seizure drugs; Consumption of antioxidant supplements.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

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 Baqiyatallah Medical Sciences University

Street address

Baqiyatallah University of Medical Science, South sheikh-Bahaei street, Mollasadra Avenue, Tehran, Iran

City

Tehran

Postal code

Approval date

2014-01-05, 1392/10/15

Ethics committee reference number

340

Health conditions studied

1

Description of health condition studied

Hyperlipidaemia

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidaemia, unspecified

Primary outcomes

1

Description

Total Antioxidant Capacity

Timepoint

Before and after Intervention

Method of measurement

ELISA

2

Description

Serum Malondialdehyde

Timepoint

Before and after Intervention

Method of measurement

Colorimetric

3

Description

GSH

Timepoint

Before and after Intervention

Method of measurement

Colorimetric

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, patients with Hyperlipidemia will receive 2 tablet of L - Carnitine (each tablet 1g) for eight weeks.

Category

Treatment - Drugs

2

Description

In the control group, patients with Hyperlipidemia will receive 2 tablet of placebo (each tablet 1g) for eight weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Health School Baqiyatallah University of Medical Sciences

Full name of responsible person
Hesam Kazemzad

Street address
Baqiyatallah University of Medical Science, South sheikh-Bahaei street, Mollasadra Avenue, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Baqiyatallah University of Medical Sciences

Full name of responsible person
Dr Gashtasb Aghasinejad

Street address
Vice chancellor for research of Baqiyatallah University of Medical Sciences, South sheikh-Bahaei street, Mollasadra Avenue, Tehran, Iran

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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, Baqiyatallah 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
Baqiyatallah University of Medical Science

Full name of responsible person
Hesam Kazemzad

Position
Nutrition and Food Hygiene

Other areas of specialty/work

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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