

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effects of L-carnitine Supplementation on Body composition, Oxidative stress and Inflammatory factors in patients with Coronary Artery Disease: A Randomized Clinical Trial

Protocol summary

Summary

This is a double blind randomized control trial. Coronary artery disease patients (stable and unstable CAD) with stenosis equal to or more than 50% in at least one of the main coronary arteries and patients who receive PTCA (angioplasty) will be selected. Patients with diabetes, thyroid disorders, liver and kidney disease are excluded from this study. After obtaining the consent of those eligible, randomly selected into two groups receiving the L-carnitine supplement and placebo. Intervention group will receive two L carnitine 500 mg tablets (made in kaern company- Iran) twice a day for 12 weeks and control group will receive quite similar tablets containing soluble starch with the same dose and time-consuming. At the beginning and end of the study 10 ml blood venous sample after 12-14 hours of fasting will be obtained. Biochemical variables including inflammatory factors (hs-CRP), oxidative stress (Nytrotirosine and myeloperoxidase), total antioxidant capacity (TAC) at baseline and again at the end of the study (12 weeks) will be examined. Anthropometric measurements and body composition (including height, weight, BMI, waist circumference and hip circumference, body fat mass, percent fat-free mass, etc.) at the beginning of the trial and the end of the sixth and twelfth weeks will be checked. To obtain information about food intake, 24-hour recall questionnaire for 3 first days of study and at the end of the sixth and twelfth weeks (for 2 typical day and a holiday) will be completed through interviews.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060528260N1**
Registration date: **2016-07-05, 1395/04/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-05, 1395/04/15

Registrant information

Name

Maryam Shabanpur

Name of organization / entity

Kermanshah University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of L-carnitine Supplementation on Body composition, Oxidative stress and Inflammatory factors in patients with Coronary Artery Disease: A Randomized Clinical Trial

Public title

Effect of L carnitine on Coronary Artery Disease Patients
Outcome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients having at least 50% stenosis of one major coronary artery or receiving percutaneous transluminal coronary angioplasty (PTCA). Exclusion criteria: The patients with diabetes, liver, or renal diseases will be excluded. The patients under medications therapy, such as acenocoumarol, thyroid hormone, and warfarin, and those currently receiving vitamin supplements will also be excluded.

Age

No age limit

Gender

Both

Phase

N/A

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, Kermanshah University of Medical Science

Street address

Shahid Beheshti Boulevard, Number 2 Building of Kermanshah University of medical science

City

Kermanshah

Postal code**Approval date**

2016-05-11, 1395/02/22

Ethics committee reference number

KUMS.RES.1395.80

Health conditions studied**1****Description of health condition studied**

Coronary Artery Disease(CAD)

ICD-10 code

I20-I25

ICD-10 code description

Ischaemic heart diseases

Primary outcomes**1****Description**

hs-CRP

Timepoint

before and after

Method of measurement

ELISA assay

2**Description**

myeloperoxidase(MPO)

Timepoint

before and after

Method of measurement

ELISA assay

3**Description**

nitrotyrosine(NT)

Timepoint

before and after

Method of measurement

ELISA assay

4**Description**

Total antioxidant capacity(TAC)

Timepoint

before and after

Method of measurement

Colorimetric assay

5**Description**

body composition

Timepoint

At first and the end of sixth and twelfth weeks of the study

Method of measurement

body Analyzers Jown Plus (Avis 333)

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

evaluation of patients diet

Timepoint

At first and the end of sixth and twelfth weeks

Method of measurement

24 hour recall questionnaire

2

Description

The level of physical activity.

Timepoint

at first and the end of sixth and twelfth weeks of study

Method of measurement

IPAQ questionnaire

3

Description

blood pressure

Timepoint

at first and the end of study

Method of measurement

By mercury sphygmomanometer

Intervention groups

1

Description

Intervention group: will receive two L carnitine 500 mg tablets (made in karen company) twice a day (with breakfast and dinner) for 12 weeks .

Category

Treatment - Other

2

Description

Control group: will receive quite similar tablets (in terms of shape and color and packaging. ..) containing soluble starch with the same dose and time-consuming

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah University of Medical Science, School of Public Health

Full name of responsible person

maryam shabanpur

Street address

Dolat abad, school of public health

City

Kermabshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Kermanshah University of Medical Sciences

Full name of responsible person

Dr. behrooz hamze

Street address

Kermanshah, Shahid Beheshti Blvd., Kermanshah University of Medical Sciences

City

Kermanshah

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 of Kermanshah 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

Kermanshah University of Medical Science, School of Public Health

Full name of responsible person

Maryaam Shabanpur

Position

MSc Student of Nutrition Science

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Assistant Professor, Department of Nutrition, School

of Public Health, Kermanshah University of Medi

Full name of responsible person

Dr Seyyed Mostafa Nachvak

Position

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Web page address

Person responsible for updating data

Contact

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