Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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 Medidcal 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
myeloproxidase(MPO)
Timepoint
before and after
Method of measurement
ELISA assay

3

Description
nitrityrosine(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
evalution of patients diet

Timepoint
At first and the end of sixth and twelfth weeks
Method of measurement
24 hour recall questionare

2

Description
The level of physical activity.
Timepoint
at first and the end of sixth and twelfth weeks of study
Method of measurement
IPAQ questionare

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