Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Evaluating the effect of L Carnitine administration on post percutaneous coronary intervention levels of Troponin I as a myocardial damage and high-sensitive C-Reactive Proteins as an Inflammatory markers

Protocol summary

Summary

The goal of this randomized clinical trial is to evaluate the effect of L-Carnitine on post PCI biomarkers of myocardial damage and Inflammation in patients undergoing elective Percutaneous Coronary Intervention(PCI). Elevated cardiac enzymes indicating myocyte damage and increased levels of CRP as inflammatory marker occurs even after elective PCI had a direct correlation with In-stent restenosis and associated with increased risk of cardiac events during follow-up. Stent placement in the coronary arteries leading to increased intimal cell proliferation and extracellular matrix production is increased in inflammatory processes. Intra-coronary stents has revolutionized interventional cardiology but continued stenosis and atherosclerosis after it is still present as a serious concern. The surgical/anesthesia trauma caused the production of reactive oxygen species. Antioxidants can prevent activation of platelets in the oxidative stress caused by free radicals. L-Carnitine decreases atherosclerosis plaques by antioxidant effects and improves cholesterol metabolism. Its positive effects in patients with chronic heart failure ¸peripheral and coronary artery disease and also myocardial infarction was due to an increase in the mechanical strength of the heart, reduce in arrhythmia, decrease in cardiac remodeling and prevention of tissue necrosis. L - Carnitine treatment has also been shown to be capable of decreasing serum cholesterol and triglycerides. In this study 100 patients were randomly placed in two groups of 50 people. In the first group of patients, at the day before catheterization 3 g L - carnitine (1 g every 8 hours) is given and lasts for up to 48 hour later. The next group will not receive the drug. In both groups, blood samples are collected and level of high sensitive C-Reactive Protein (hs-CRP) and Troponin I (TnI) at baseline ¸24 and 48 hour after catheterization will be measured

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302088698N10**
Registration date: **2013-03-08, 1391/12/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-03-08, 1391/12/18

Registrant information

Name

Azita Hajhossein Talasaz

Name of organization / entity

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the effect of L Carnitine administration on post percutaneous coronary intervention levels of Troponin I as a myocardial damage and high-sensitive C-Reactive Proteins as an Inflammatory markers

Public title
Impact of l-carnitine on levels of myocardial damage and inflammation biomarkers after percutaneous coronary intervention

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:Patients with ischemic heart disease that have more than 50 percent occlusion in angiography findings and candidates for elective Pecrcutaneous Coronary Intevention.Exclusion criteria: cardiogenic shock;ST Elevation Myocardial Infarction;pregnant and lactating womens;patients under 18 years;immunologic or hematologic disorders;current infection;chronic kidney disease;serum creatinine above 2.5 mg/dl;hypothyroidism;epilepsy or convulsion;chronic liver disease;cancer

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
16 Azar St., Qhods St., Tehran University of Medical Sciences

City
tehran

Postal code

Approval date
2012-11-07, 1391/08/17

Ethics committee reference number
19354

Health conditions studied

1

Description of health condition studied
ischemic heart disease

ICD-10 code
I20-I25

ICD-10 code description
Myocardial ischemia followed by decreased oxygen to the myocardium

Primary outcomes

1

Description
high sensitive C--Reactive protein

Timepoint
baseline¸24 and 48 hours after

Method of measurement
Elisa kit

2

Description
troponin I

Timepoint
baseline¸24 and 48 hours after

Method of measurement
Elisa kit

Secondary outcomes

empty

Intervention groups

1

Description
In the first group of patients, at 24 hour before catheterization 3 g L - carnitine (1 g every 8 hours) is given and lasts for up to 48 hour later. blood samples at baseline ¸24 and 48 hour after catheterization are collected and level of high sensitive C-Reactive Protein (hs-CRP) and Troponin I (TnI) will be measured

Category
Treatment - Drugs

2

Description
Medication will not be given to patients in the control

group. Patients blood sample is collected at baseline and 24 hour after catheterization.Patients blood sample is collected at baseline ¸24 and 48 hour after catheterization and levels ofCRP and TnI will be measured.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Heart Center

Full name of responsible person
Mohammad Alidousti

Street address
North Kargar St., Jalal Al Ahmand St

City
tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ms. Fatemeh Saeedi

Street address
16 Azar St., Qhods St, Tehran University of Medical Sciences

City
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Azita Hajhossein Talasaz

Position
Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Azita Hajhossein Talasaz,Mohammad Alidousti

Position
assistant professor-associated professor

Other areas of specialty/work

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Person responsible for updating data

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Tehran University of Medical Sciences

Full name of responsible person
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Resident of Cardiology

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