# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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
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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

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tehran

**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

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assistant professor-associated professor

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## Person responsible for updating data

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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*