

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Impact of L-carnitine on biomarkers of platelet activation in patients undergoing elective Percutaneous Coronary Intervention(PCI)

Protocol summary

Summary

The goal of this randomized clinical trial is evaluation of impact of L-carnitine on biomarkers of platelet activation in patients undergoing elective Percutaneous Coronary Intervention(PCI). The main problem of coronary angioplasty is restenosis and acute occlusion. Restenosis after percutaneous transluminal coronary angioplasty (PTCA) is occurred secondary to an overreaction of normal processes by the inherent inflammatory response to the mechanical traumatic tension of the arterial wall. L-carnitine decrease activation of NADPH oxidase via inhibition of arachidonic acid. NADPH oxidase is a platelet-activating enzyme. Due to increased oxidative stress and activation of platelets by several mediators and subsequently restenosis after coronary angioplasty, it is assumed that L - carnitine can help prevent this process. Patients with ischemic heart disease that have more than 50 percent occlusion in angiography findings and candidates for elective Percutaneous Coronary Intervention are included and patients with ST Elevation Myocardial Infarction or under 18 years and others complications such as cancer or renal and hepatic dysfunctions are excluded from the study. 80 patients were randomly placed in two groups of 40 people (intervention and control group). The first group of patients, 3 g L - carnitine (1 g every 8 hours) is given at 1 day before catheterization and lasts for up to 24 hour after it. The next group will not receive the drug. In both groups, blood samples are collected and biomarkers of platelet activation such as CD40L, P-selectin and TGF- β at baseline and 24 hour after catheterization will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212178698N4**

Registration date: **2013-01-10, 1391/10/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-10, 1391/10/21

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-12-30, 1391/10/10

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of L-carnitine on biomarkers of platelet activation in patients undergoing elective Percutaneous Coronary Intervention(PCI)

Public title

Impact of l-carnitine in percutaneous coronary intervention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with ischemic heart disease that have more than 50 percent occlusion in angiography findings and candidates for elective Percutaneous Coronary Intervention. Exclusion criteria: cardiogenic shock; ST Elevation Myocardial Infarction; pregnant and lactating women; 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 **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

transforming growth factor beta (TGF- β)

Timepoint

baseline and 24 hour after

Method of measurement

Elisa kit

2**Description**

CD40L

Timepoint

baseline and 24 hour after

Method of measurement

Elisa kit

3**Description**

P-Selectin

Timepoint

baseline and 24 hour after

Method of measurement

Elisa kit

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

Major adverse cardiac events (MACE)

Timepoint

1 month later

Method of measurement

evaluation of patient condition such as death, stent thrombosis confirmed by angiography, acute coronary syndrome defined by AHA, again revascularization with angioplasty or bypass

Intervention groups**1****Description**

3 gram L - carnitine is administered to intervention patients one day before catheterization (1 g every 8

hours) and lasts for up to 24 hour after it (for two days). Patients blood sample is collected at baseline and 24 hour after catheterization and biomarkers of platelet activation such as CD40L, P-selectin and TGF- β 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.

Category

Other

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.

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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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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

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Position

Assistant Professor

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