

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Impact of L-carnitine on contrast induced nephropathy 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 contrast induced nephropathy in patients undergoing elective Percutaneous Coronary Intervention(PCI). Acute kidney injury after cardiac surgery and coronary angiography is one of the main problems arising for these patients. Based on severity of kidney failure, in these patients mortality is 3 to 9 times higher than normal patients. The mechanisms are listed for development of AKI include endogenous and exogenous toxins ,metabolic factors , ischemia and reperfusion,neurohormonal activity and inflammation and oxidative stress.Several studies found that urinary NGAL has been increased faster and has higher sensitivity and accuracy of the renal biomarkers. Under ischemic conditions and oxidative stress, it is assumed that L - Carnitine can help prevent the incidence of acute renal failure by antioxidant effects and improving circulation.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. 320 patients were randomly placed in two groups of 160 people. The first group of patients, 3 g L - carnitine (1 g every 8 hours) is given at the day before catheterization and lasts for up to 48 hour after it. The next group will not receive the drug. In both groups, blood samples are collected and biomarker of renal function such as urine NGAL at baseline and 12 hour after catheterization will be measured. Also, serum creatinine and glomerular filtration rate will be measured at baseline and 48 hours after catheterization.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201212178698N5**

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

Azita Hajhossein Talasaz

###### Name of organization / entity

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

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Iran (Islamic Republic of)

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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 contrast induced nephropathy in

patients undergoing elective Percutaneous Coronary Intervention(PCI)

**Public title**

Impact of l-carnitine on contrast induced nephropathy

**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**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **320**

**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**

(Neutrophil gelatinase-associated lipocalin (NGAL

**Timepoint**

baseline and 12 hour after

**Method of measurement**

Elisa kit

**2****Description**

(Glomerular Filtration Rate (GFR

**Timepoint**

baseline and 48 hour after

**Method of measurement**

determination of serum creatinine by chromatography

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

Renal function

**Timepoint**

1 month later

**Method of measurement**

evaluation of patient condition such as death and renal function

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

3 gram L - carnitine is administrated to intervention patients one day before catheterization (1 g every 8 hours) and lasts for up to 48 hour after it (for three days). Patients urine sample is collected at baseline and 12 hour after catheterization for determination of NGAL. Also serum creatinine and glumerular filtration is determined at baseline and 48 hour after catheterization.

**Category**

Treatment - Drugs

2

**Description**

Medication will not be given to patients in the control group. Patients urine sample is collected at baseline and 12 hour after catheterization for determination of NGAL. Also serum creatinine and glomerular filtration is determined at baseline and 48 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.

**City**

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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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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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Resident

**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*