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 Pecrcutaneous Coronary Intevention 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

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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 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 **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 glumerular 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
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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
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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

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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