Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of L-Carnitine on the Prevention of Contrast Induced Nephropathy in Patients Undergoing Coronary Angiography in Heshmat Hospital in 2017:a Randomized Clinical Trial

Protocol summary

Study aim

Determination of the effect of L-carnitine on the prevention of contrast-induced nephropathy in patients undergoing angiography

Design

The two study groups will include the group receiving the drug, L-carnitine and the non-receiving drug group. Patients will be evaluated after the procedure for CIN occurrence. The patient's GFR will be calculated using the MDRD equation according to SrCr.In the study of wenhua and colleagues, The incidence of contrast-induced nephropathy was reported in the group receiving L-carnitine and control group of 6.9% and 19.2%, respectively. Accordingly, with the assumption of α = 0.05 and ß = 0.20, 114 samples obtaine the sample size from each group . Considering 20% of the missing data, the number of required samples in each group will rise to 143 Samples .

Settings and conduct

This study will be conducted in the form of Prospective Randomized Controlled Trial in D.R Heshmat Educational Medical Research Center in Rasht.

Participants/Inclusion and exclusion criteria

Inclusion criteria:All patients who undergo elective angiography and PCI after approval plan in 2017 will be located at D.R Heshmat Educational Medical Research Center; Exclusion criteria: ST elevation MI in Pregnancy; History of CABG within 6 months ago; History of PCI within 6 months ago; Cardiogenic shock; Simultaneous use of nephrotoxic drugs ; exposuring to contrast material (from 2 days before 2 days later); Renal transplantation History; Thyroid and Corticosteroids disorders; LVEF<35%; Patients who have not received full doses of medication after entering the study due to digestive complications or incompleteness of the drug will be excluded from the study.

Intervention groups

L-Carnitine drug Receiving Group control group

Main outcome variables

It reduces the complications of angiography and morbidity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180921041079N1**
Registration date: **2019-03-19, 1397/12/28**
Registration timing: **retrospective**

Last update: **2019-03-19, 1397/12/28**
Update count: **0**

Registration date

2019-03-19, 1397/12/28

Registrant information

Name

Abdul Hassan Sancholy tazh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3366 3070

Email address

e.ramezanzade@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of L-Carnitine on the Prevention of Contrast Induced Nephropathy in Patients Undergoing Coronary Angiography in Heshmat Hospital in 2017:a Randomized Clinical Trial

Public title

The Effect of L-Carnitine on the Prevention of Contrast Induced Nephropathy in Patients Undergoing Coronary Angiography in Heshmat Hospital in 2017

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who Undergo Elective Angiography and PCI After Approval of the Plan in 1396 Will be Located at Rasht Medical Center. Patient Satisfaction: The Willingness to Participate in the Study and Sampling

Exclusion criteria:

ST elevation MI Pregnancy History of CABG in the last 6 months History of PCI in the last 6 months Cardiogenic shock Simultaneous use of nephrotoxic drugs Recent exposure to contrast material (from 2 days before 2 days later) Renal transplantation biography Thyroid disorders Corticosteroids LVEF<35% Patients who have not received full doses of medication after entering the study due to Digestive complications or incompleteness of the drug will be excluded from the study.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **143**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of guilan University of Medical Sciences

Street address

Dr. Heshmat Rasht Hospital -Masala Square, Baniyan St.

City

Rasht

Province

Guilan

Postal code

413955588

Approval date

2018-06-11, 1397/03/21

Ethics committee reference number

IR.GUMS.REC.1397.107

Health conditions studied

1

Description of health condition studied

Cardiac patients are candidates for angiography

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Contrast Nephropathy

Timepoint

L carnitine is given 24 hours before coronary angiography and then every 8 hours

Method of measurement

Serum creatinine, Glomerular filtration degree, Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: From the 24 hours before the coronary artery bypass graft surgery, 3000 milligrams of L-carnitine solution (1 g per 10 ml) will be given at intervals of 8 hours. After the procedure, within 24 hours, the dietary intake of L-carnitine will be 3000 mg (1000 mg three times a day). Since oral intake of carnitine is saturated in 2 grams, the doses are given in divided

doses, also routine care (hydration with N.S. serum)is done.

Category

Prevention

2

Description

Control group: The control group does not receive L-carnitine and only routine care is provided.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hashmat hospital

Full name of responsible person

Abdulhassan SanchulyTaze

Street address

Maslieh Square., Bayani Ave, Rasht Town; Dr. Heshmat Hospital

City

Rasht

Province

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Postal code

4193955588

Phone

+98 13 3361 8177

Email

E.Ramezanzade@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Shadman Nemati

Street address

University of Technology Research and Technology, Old Building School of Health, Faced to the 17th Shahrivar Hospital, Shahid Siadati St, Namjoo Ave, Rasht,

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Province

Guilan

Postal code

4144666949

Phone

+98 13 3333 5821

Email

research@gums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Abdulhassan schnuculy taze

Position

Cardiovascular Assistant

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Intervention group receiving L-Carnitine
When the data will become available and for how long
24 hours before coronary angiography, then every 8 hours
To whom data/document is available
For researchers working in academic and scientific institutions
Under which criteria data/document could be used
To prevent nephropathy
From where data/document is obtainable
Heshmat Rasht Hospital
What processes are involved for a request to access data/document
Through automation correspondence or email
Comments