Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of N-Acetyle Systeine in preventing contrast induced nephropathy in patients with different stages of chronic kidney diseases

Protocol summary

Summary

Contrast induced nephropathy(CIN) is the third cause of acute kidney injury(AKI) in hospitalized patients. It is associated with high rate of morbidity and mortality. Prevention is the only modality for managing this disorder and although many studies have been performed in this regard, there are many controversies about the preventing measures. One of the most controversies in preventing of this disorder is about the role of N-Acetyle cystein. In our study 732 adult patients with chronic kidney disease whom undergo coronary angiography/angioplasty will be randomly allocated into 4 groups. Two of them recieved N-acetyl cystein orally or intravenously respectively and two other groups will recieve placebo either orally or intravenously. The study is anticipated to complete in one year. The contrast nephropathy is defined as 25% increase in serum creatinine frome the base.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205305113N3**
Registration date: **2012-06-24, 1391/04/04**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-06-24, 1391/04/04

Registrant information

Name

Seyyed Mohammad Reza Khatami

Name of organization / entity

Nephrology Research Center, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2659

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khatamis@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

The research grant budget of nephrology research center of Tehran University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

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

The effect of N-Acetyle Systeine in preventing contrast induced nephropathy in patients with different stages of chronic kidney diseases

Public title

N- Acetyle Systeine and Contrast nephropathy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age more than 18; serum creatinine more than 1.5 mg/ dl ; not having AKI; not receiving nephrotoxine since 1 week before entering the study; signing the consent. Exclusion criteria: the patients who undergo surgery in less than 1 week of contrast exposure; the patients who are in need for a nephrotoxine in less than five days after contrast exposure; the patients who need repeated contrast

administration in less than five days of first exposure

Age
From **18 years** old to **99 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **549**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
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
Keshavarz Blvd.

City
Tehran

Postal code

Approval date
2012-05-21, 1391/03/01

Ethics committee reference number
12345

Health conditions studied

1

Description of health condition studied
Nephropathy due to contrast agents

ICD-10 code
N99.0

ICD-10 code description
Postprocedural renal failure

Primary outcomes

1

Description
serum creatinine

Timepoint
The second day and five days after contrast exposure

Method of measurement
Serum creatinine in plasma

Secondary outcomes

1

Description
Hypersensitivity to contrast

Timepoint
Immediately after exposure to contrast

Method of measurement
Physical conditions

Intervention groups

1

Description
Intervention1: ampule N-acetyl cystein 1200 mg intravenously half an hour before contrast administration

Category
Prevention

2

Description
Intervention 2: Tablet N-acetyl cystein 600 mg bid, starting from the day before contrast administration and continued until the day after that.

Category
Prevention

3

Description
Control1: intravenous saline 3 cc half an hour before contrast administration

Category
Placebo

4

Description
Control2: Placebo tablet bid starting the day before contrast administration and continue until the day after that.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Heart Center

Full name of responsible person
Mohammad Reza Khatami

Street address

Transplany unit, Imam Khomeini Hospital, Keshavarz Blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nephrology Research Center, Tehran University of Medical Sciences

Full name of responsible person

Mahboob lessan pezeshki

Street address

Imam Khomeini hospital, Keshavarz Blvd.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Nephrology Research Center, 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

Nephrology Research Center

Full name of responsible person

Mohammad Reza Khatami

Position

Associate 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