Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Standard vs double dose of N-acetylcysteine to prevent contrast indused nephropathy in admitted patients in the angiography department with Glomerular Filtration Rate˂60 ml/min, in Kowsar hospital of Semnan

Protocol summary

Summary

Objective: the effect of standard dose and twice the standard dose of N-acetylcysteine in prevention of contrast medium reception-induced nephropathy. The study population: the patients with GFR ≤ 60 ml/minute from from baseline of study to one year after that be candidates for coronary angiography in angiography department of Semnan Kowsar hospital. Inclusion criteria: aged 18 and older; glomerular filtration rate less than 60 ml. Exclusion criteria: pregnant women; lactating mother; dialysis patients; blood pressure; baseline serum creatinine level greater than 7 mg/dL; severe valvular heart disease; autoimmune disorders; acute or chronic diseases; get contrast media in 10 days ago. Sample size, intervention, intervention time, outcome of study: sample size of this study is 154 persons in 2 group of 77 peoples as intervention 1 and 2. The intervention group 1: oral N-acetylcysteine with standard dose + 0/9% saline infusion. The intervention group 2: oral N-acetylcysteine with twice the standard dose + 0/9% saline infusion. Measurement of serum creatinine levels will be performed before experiment and 24, 48 and 72 hours after receiving contrast medium in Semnan Kowsar hospital. Hemoglobin and Hematocrit, fasting blood sugar and also ejection fraction from the medical records of individuals is extracted and notes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052925732N16**
Registration date: **2017-06-07, 1396/03/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-07, 1396/03/17

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2016-07-13, 1395/04/23

Expected recruitment end date

2017-07-13, 1396/04/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Standard vs double dose of N-acetylcysteine to prevent contrast indused nephropathy in admitted patients in the angiography department with Glomerular Filtration Rate˂60 ml/min, in Kowsar hospital of Semnan

Public title

Standard vs double dose of N-acetylcysteine to prevent contrast indused nephropathy in admitted patients in the

angiography department with Glomerular Filtration Rateˇ60 ml/min, in Kowsar hospital of Semnan

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: aged 18 and older; glomerular filtration rate less than 60 ml. Exclusion criteria: pregnant women; lactating mother; dialysis patients; blood pressure; baseline serum creatinine level greater than 7 mg/dL; severe valvular heart disease; autoimmune disorders; acute or chronic diseases; get contrast media in 10 days ago; sensitivity to contrast media or N-acetylcysteine; oliguria (the urine volume less than 400 cc in 24 hours); acute heart failure with preserved ejection fraction <35%; receive supplements of vitamin C in the past week.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **154**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences, Deputy of research and technology, Ethics Committee

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Postal code

3514799442

Approval date

2016-07-13, 1395/04/23

Ethics committee reference number

IR.SEMUMS.REC.1395.78

Health conditions studied

1

Description of health condition studied

nephropathy

ICD-10 code

N08.3

ICD-10 code description

Diabetic nephropathy

Primary outcomes

1

Description

Serum creatinine levels

Timepoint

Before the intervention, 24, 48 and 72 hours after the intervention.

Method of measurement

Laboratory

2

Description

BUN levels

Timepoint

Before the intervention, 24, 48 and 72 hours after the intervention.

Method of measurement

Laboratory

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group 1: oral N-acetylcysteine with standard dose + 0/9% saline infusion: Received oral N-acetylcysteine, 600 mg daily, twice a day for two days (the day before receiving the contrast media + on day receiving the contrast agent) + receiving 0/9% saline infusion for 100 ml per hour, from 6 hours before receiving the contrast media and 12 hours later.

Category

Treatment - Drugs

2

Description

The intervention group 2: oral N-acetylcysteine with twice the standard dose + 0/9% saline infusion: Received oral N-acetylcysteine, 1200 mg daily, twice a day for two days (the day before receiving the contrast media + on day receiving the contrast agent) + receiving 0/9% saline infusion for 100 ml per hour, from 6 hours before receiving the contrast media and 12 hours later.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital
Full name of responsible person
Maryam Tavallaei
Street address
Kosar Hospital, Street Amin, Semnan
City
Semnan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences, Vice Chancellor for Research and Technology
Full name of responsible person
Mohammadreza Asgari
Street address
Semnan University of Medical Sciences, Deputy of Research and Technology, Basij Blvd, Semnan
City
Semnan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan University of Medical Sciences, Vice Chancellor for Research and Technology
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
Semnan University of Medical Sciences
Full name of responsible person
Dr Maryam Tavallaei
Position
Internal Medicine
Other areas of specialty/work
Street address
Semnan University of Medical Sciences, Blvd Basij, Semnan
City
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Fax
+98 23 3344 8999
Email
are20935@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Maryam Tavallaei
Position
Internal Medicine
Other areas of specialty/work
Street address
Semnan University of Medical Sciences, Blvd Basij, Semnan
City
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Fax
+98 23 3344 8999
Email
are20935@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr Maryam Tavallaei
Position
Internal Medicine
Other areas of specialty/work
Street address
Semnan University of Medical Sciences, Blvd Basij, Semnan
City
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Fax
+98 23 3344 8999

Email
are20935@gmail.com
Web page address

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