

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Standard vs double dose of N-acetylcysteine to prevent contrast induced nephropathy in admitted patients in the angiography department with Glomerular Filtration Rate $\leq$ 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  $\leq$  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

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Iran (Islamic Republic of)

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+98 23 3345 1336

###### Email address

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##### 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 induced nephropathy in admitted patients in the angiography department with Glomerular Filtration Rate  $\leq$  60 ml/min, in Kowsar hospital of Semnan

##### Public title

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

angiography department with Glomerular Filtration Rate  $\leq$  60 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,  
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**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*