

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Effect of N-acetyl Cysteine (NAC) on contrast-induced nephropathy in patients with basal urinary neutrophil gelatinase-associated lipocalin (NGAL) positive underwent angiography or coronary intervention (PCI): A single blind randomized clinical trial

Protocol summary

Study aim

Effect of N-acetyl Cysteine on contrast-induced nephropathy in patients with basal urinary neutrophil gelatinase-associated lipocalin positive underwent angiography or coronary intervention

Design

Clinical trial, Phase 3, Have control group, with parallel groups, single blind, Sample size 110, Permuted block randomization

Settings and conduct

This study will be carried out using clinical trial in Farshchian Cardiovascular Hospital, Hamadan

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 90 years, Under angiography or coronary artery intervention Exclusion criteria: Kidney disease, Urinary tract infection, Urinary tract tumor, Use of Nephrotoxic or Antibiotic drugs or contrast media within past week

Intervention groups

Intervention group: intravenous hydration 2 to 3 cc per kilogram and N-acetylcysteine oral 1200 mg twice daily for 3 days. control group: intravenous hydration 2 to 3 cc per kilogram

Main outcome variables

Creatinine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190311043011N1**

Registration date: **2019-03-17, 1397/12/26**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-17, 1397/12/26**

Update count: **0**

Registration date

2019-03-17, 1397/12/26

Registrant information

Name

Azadeh Mozayani Monfared

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1731

Email address

azadeh_m27@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-11, 1397/12/20

Expected recruitment end date

2019-09-11, 1398/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of N-acetyl Cysteine (NAC) on contrast-induced nephropathy in patients with basal urinary neutrophil gelatinase-associated lipocalin (NGAL) positive underwent angiography or coronary intervention (PCI): A single blind randomized clinical trial

Public title

Effect of N-acetyl Cysteine (NAC) on contrast-induced nephropathy in patients with basal urinary neutrophil gelatinase-associated lipocalin (NGAL) positive underwent angiography or coronary intervention (PCI): A single blind randomized clinical trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 90 years Undergoing angiography or coronary artery intervention

Exclusion criteria:

Kidney disease Urinary tract infection Urinary tract tumor
Use of Nephrotoxic or Antibiotic drugs or contrast media within past week

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **110**

More than 1 sample in each individual

Number of samples in each individual: **3**

one urine sample, two blood sample

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose, we will use four random blocks method. For this purpose, we will prepare four paper sheets. On the two sheets of the letter "I" means "Intervention" and on the other two letters "C" meaning "Control". we will mix the sheets and place them in the drawer. For each eligible patient, one of the sheets will be drawn randomly and based on the letter I or C, patient will be assigned to one of the two groups. It should be noted that the drawn sheets will not be returned to the drawer until all four sheets will be drawn out. After all four sheets will be drawn, all will be returned to the drawer and above process will continue until the sample size will be reached.

Blinding (investigator's opinion)

Single blinded

Blinding description

The laboratory will be unaware of the patient receiving or not receiving the drug, so the study will be done single blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, SHahid Fahmideh Blvd

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2019-03-10, 1397/12/19

Ethics committee reference number

IR.UMSHA.REC.1397.964

Health conditions studied

1

Description of health condition studied

Contrast- Induced Nephropathy disease

ICD-10 code

N17.8

ICD-10 code description

Other acute kidney failure

Primary outcomes

1

Description

Serum creatinine

Timepoint

Before and 48 hours after the intervention

Method of measurement

blood test

2

Description

Neutrophil Gelatinase Associated Lipocalin

Timepoint

Before the intervention

Method of measurement

Urine Test

Secondary outcomes

empty

Intervention groups

1

Description

Oral acetylcysteine (NAC) tablet of 1200 mg twice daily for 3 days
Category
Prevention

2

Description
Control group: Venous hydration 2-3cc / kg
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian heart hospital
Full name of responsible person
Azadeh Mozayani Monfared
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
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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

Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Azadeh Mozayani Monfared
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

We are not collecting data

When the data will become available and for how long

one year

To whom data/document is available

No decision has been made yet

Under which criteria data/document could be used

No decision has been made yet

From where data/document is obtainable

Research Center of farshchian heart center

What processes are involved for a request to access data/document

Presentations letter from the University Research Center

Comments