Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of efficacy of Nicorandil on incidence of contrast-induced nephropathy in patients with GFR < 60% and undergoing coronary angiography and percutaneous coronary intervention- A randomized clinical trial

Protocol summary

Study aim

Evaluation of efficacy of Nicorandil for prevention of contrast-induced nephropathy in patients undergoing coronary angiography and percutaneous coronary intervention

Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial for 264 patients. The website http://www.randomization.com/ will be used for randomization.

Settings and conduct

This study will be conducted on patients who are candidates for CAG or PCI in Heshmat Rasht Hospital The study will be single blind and only the patients will be unaware of the treatment method of the other group.

Participants/Inclusion and exclusion criteria

Patients with GFR less than 60 who are not on dialysis and are candidates for non-emergenct CAG or non-primary PCI and have 24 hours of drug therapy with nicorandil will be included in the study. And patients who have received metformin, ARB, ACEI, nicorandil, nitrocantine, sildenafil and other phosphodiesterase 5 (PDE5) inhibitor family drugs in the last 24 hours and have urinary tract infection will not be included in the study.

Intervention groups

In the control group, patients will be hydrated with 0.45% saline serum in the form of 50 cc per hour from 24 hours before the procedure to 24 hours after, and they will be given N-acetylcysteine 1200 mg orally every 12 hours. It will be given from 24 hours before to 24 hours after the procedure. In the intervention group, patients will be hydrated with 0.45% saline serum in the form of 50 cc per hour from 24 hours before the procedure to 24 hours after, and they will be given 1200 mg N-acetylcysteine tablets orally every 12 hour from 24 hours before to 24 hours after the procedure. Also, in the intervention group, patients will receive Nicorandil 10 mg tablets every 12 hours from 24 hours before to 24 hours after the procedure.

Main outcome variables

Creatinine level- BUN level- urinary output

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230110057096N1**
Registration date: **2023-02-10, 1401/11/21**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-10, 1401/11/21**
Update count: **0**

Registration date

2023-02-10, 1401/11/21

Registrant information

Name
Arsalan Salari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 13 3361 8177
Email address
gums.icrc@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2024-02-04, 1402/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of Nicorandil on incidence of contrast-induced nephropathy in patients with GFR < 60% and undergoing coronary angiography and percutaneous coronary intervention- A randomized clinical trial

Public title

Effect of Nicorandil on contrast-induced nephropathy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with GFR<60 ml/min that do not undergo dialysis Patients who are a candidate for non-emergent CAG or non-primary PCI and have 24-hour time for treatment with Nicorandil

Exclusion criteria:

Consuming Metformin, ACEI, ARB, Nicorandil, Nitrocontin, Sildenafil and other phosphodiesterase 5 inhibitors in the last 24 hours having urinary tract infection(UTI)

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **264**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of sampling and randomization of this clinical trial study will be the blocked randomization method. In this way, each person will be randomly placed in the intervention and control group using blocks of 4 randomly in a ratio of 1:1. Letters A and B will be assigned to each group. The website http://www.randomization.com/ will be used for randomization. The list of codes obtained from this website will be provided to the researchers of the project, and every patient who meets the conditions for entering the study will be entered into the study according to the assigned code A, B respectively. For concealment in this research, simple random allocation concealment method will be used on the study participants. In this way, each patient will be assigned a code. In this method, each of the generated random codes will be written on a card. Then they will be placed inside sealed opaque envelopes in random order. In order to maintain the random sequence, the outer surface of the envelopes will be numbered in the same order. Finally, the lid of the letter envelopes will be glued and will be placed in a box respectively. At the time of sampling, based on the order of entry of qualified participants into the study, one of the envelopes will be revealed in the order of opening and the assigned group of that participant.

Blinding (investigator's opinion)

Single blinded

Blinding description

Our study will be one-sided blind. Due to ethical issues, we cannot hide the type of treatment from the patients, so the patients are aware of the type of treatment they will receive (being in the intervention or control group). But to avoid bias in the results, the outcome evaluator (data analyst) does not know which groups the patients belong to. The groups can be specified by coding so that the analyst does not understand.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in research of Guilan University of Medical Sciences

Street address

Vice President of Research and Technology of Guilan University of Medical Sciences, in front of 17sharivar Hospital,Shahid Siadati Ave., Namjoo Blvd., Rasht, Guilan

City

Rasht

Province

Guilan

Postal code

4144666949

Approval date

2022-12-21, 1401/09/30

Ethics committee reference number

IR.GUMS.REC.1401.504

Health conditions studied

1

Description of health condition studied

contrast-induced nephropathy

ICD-10 code

ICD 10- N1

ICD-10 code description

Nephropathy induced by other drugs, medicaments and biological substances

Primary outcomes

1

Description

creatinine level

Timepoint

Measuring level of creatinine on the days 0-3-5

Method of measurement

Creatinine measurement will be done with the help of a quantitative detection kit for creatinine in serum, plasma or urine with the photometric method of Pars Azmoun company and with the callimetric method without removing proteins based on the JAFFE method.

2

Description

BUN level

Timepoint

Measuring level of BUN on the days 0-3-5

Method of measurement

BUN will be measured with the help of Urea UV quantitative detection kit in serum, plasma and urine with the photometric method of Pars Azmoun company and with the enzyme method based on the Urease-GLDH method.

3

Description

urinary output

Timepoint

Measuring urinary output on the days 0-3-5

Method of measurement

The amount of urinary output is calculated by measuring the volume of a person's urine

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In the control group standardad treatment is used and we do not use placebo. as standard treatment tab NAC 1200 mg/po/BD is given to the patients. we also hydrate the patients with half saline 50cc/h from 24 hours before to 24 hours after the procedure . we use NAC from SanaMed pharmaceutical co.

Category

Prevention

2

Description

Intervention group: in the intervention group as standard treatment tab NAC 1200 mg/po/BD is given to the patients. we also hydrate the patients with half saline 50cc/h from 24 hours before to 24 hours after the procedure . also tab Nicorandil 10 mg/po/BD is given to the patients from 24 hours before to 24 hours after the procedure. we use NAC from SanaMed pharmaceutical co. and Nicorandil from rivopharm

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmat Hospital

Full name of responsible person

Arsalan Salari

Street address

Next to the management and planning organization of Gilan province, 15 khordad st, Rasht, Guilan

City

Rasht

Province

Guilan

Postal code

4193955588

Phone

+98 13 3366 9064

Email

Gums.icrc@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

MohammadReza Naghi pour

Street address

Vice President of Research and Technology of Guilan University of Medical Sciences, in front of 17sharivar Hospital,Shahid Siadati Ave., Namjoo Blvd., Rasht, Guilan

City

Rasht

Province

Guilan

Postal code

41446-66949

Phone

+98 13 3333 6395

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
Arsalan Salari
Position
professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
Street address
Next to the management and planning organization of Gilan province, 15 Khordad st., Rasht
City
Rasht
Province
Guilan
Postal code
4193955588
Phone
+98 13 3366 9064
Email
gums.icrc@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Arsalan Salari
Position
professor
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Phone
+98 13 3366 9064
Email
gums.icrc@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Arsalan Salari
Position
professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
After the start of the project, documentation will be sent by the project manager
When the data will become available and for how long
1 week

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

by SPSS

From where data/document is obtainable

Project Manager

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

The project manager will email and send the documentation through SPSS within a week.

Comments