Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the oral Nicorandil effect on reducing the contrast-induced nephropathy incidence in cardiac catheterization patients: a randomized controlled clinical trial

Protocol summary

Study aim

Determination of the effect of Nicorandil in the prevention of contrast-induced nephropathy in patients with at least two risk factors for contrast nephropathy

Design

The envelope method will be used for random allocation in this study. 344 small cards are placed in a large envelope, from 1 to 344 is written on the cards. Numbers 1 to 172 will belong to the Nicorandil group and numbers 173 to 344 will belong to the control group.

Settings and conduct

This study is a randomized controlled and open-labeled clinical trial performed in the angiography department of Imam Reza Hospital. Eligible patients are divided into control and intervention groups (nicorandil) using a list of random numbers.

Participants/Inclusion and exclusion criteria

Admission requirements: based on score risk. Renal failure GFR (less than 60) Serum creatinine baseline above 1.5 mg/dl and no pregnancy. Minimum age 18. Diabetes mellitus. EF less than 40. Conditions of non-entry: pregnancy. Pulmonary edema. Cardiogenic shock. Multiple myeloma. Acute renal failure. ESRD (GFR <15mg / dl). Allergy to media contrast. Allergy to nicorandil. Meeting with media contrast in the last 7 days. And mannitol and phenol dopamine in the last 48 hours

Intervention groups

In the intervention group from 2 hours before to 24 to 48 hours after the procedure, oral nicorandil 10 mg 3 times a day, and intravenous normal saline from 2 hours before to 6 hours after the procedure is given to patients. In the control group, intravenous normal saline (1 ml/kg/hr) is given to patients from 2 hours before to 6 hours after the procedure.

Main outcome variables

Laboratory parameters such as Hb, FBS, HCT, TG, LDL, HDL, ChoL as well as creatinine and creatinine clearance and BUN

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210620051631N1**
Registration date: **2021-12-19, 1400/09/28**
Registration timing: **prospective**

Last update: **2021-12-19, 1400/09/28**
Update count: **0**

Registration date

2021-12-19, 1400/09/28

Registrant information

Name

Alireza Abdollahi Moghaddam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2097

Email address

abdollahiar@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the oral Nicorandil effect on reducing the contrast-induced nephropathy incidence in cardiac catheterization patients: a randomized controlled clinical trial

Public title

Evaluation of the oral Nicorandil effect on reducing the contrast-induced

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Based on the risk score,Have a moderate risk or at least two risk factors for contrast nephropathy. EF less than 40 Diabetes mellitus. Blood pressure above 140/90 mm Hg, Renal failure (GFR) less than 60 No pregnancy (basal serum creatinine above 1.5 mg / dl) Minimum age 18

Exclusion criteria:

Pregnancy Pulmonary edema Cardiogenic shock Multiple myeloma Acute renal failure ESRD(GFR<15 mg/dl) Allergy to media contrast Nicorandil allergy Facing media contrast in the last 7 days NAC and metformin and dopamine and sodium bicarbonate and mannitol and phenol dopam in the last 48 hours

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **344**

Randomization (investigator's opinion)

Randomized

Randomization description

This is how the envelopes will be prepared and printed by one of the research team members, and random numbers with the help of the Randomaize.com site will be placed inside the envelope. The lid of the envelope will be closed and its contents will not be visible from the outside. Then, the purpose of the study is first explained to the person who meets the conditions, and the person, if desired, signs the informed consent form and takes an envelope, and then opens it and enters the intervention or control group based on the contents of the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

The subjects and those evaluating the outcome will be unaware of the intervention and control groups. Eligible patients are divided into control and intervention groups (nicorandil) using a list of random numbers. Those who evaluate the outcome consist of people who work at the center and have no knowledge of the researchers' research and will make a secret assignment for the research themselves.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Imam Reza Hospital Square. Imam Reza Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

13944_91388

Approval date

2021-03-14, 1399/12/24

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.829

Health conditions studied

1

Description of health condition studied

cardiac catheterization

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Laboratory banksHb, FBS, HCT, TG, LDL, HDL,ChoL

Timepoint

The first step at the beginning of the study

Method of measurement

Sampling

Secondary outcomes

1

Description

Serum creatinine and creatinine clearance and BUN

Timepoint

It is measured 24 to 48 hours after the procedure.

Method of measurement

Protocol based analysis

Intervention groups

1

Description

Intervention group: from 2 hours before to 24 to 48 hours after the procedure, oral nicorandil 10 mg 3 times a day, and intravenous normal saline from 2 hours before to 6 hours after the procedure are given to patients.

Category

Treatment - Other

2

Description

Control group: In the control group, intravenous normal saline (1 ml / kg / hr) was given to patients from 2 hours before to 6 hours after the procedure.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Sadegh Alavi

Street address
Imam Reza Hospital Square. Imam Reza Hospital, Heart Department

City
Mashhad

Province
Razavi Khorasan

Postal code
13944_91388

Phone
+98 51 3843 6827

Email
alavisadegh157@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Majid Ghayour

Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City
Mashhad

Province
Razavi Khorasan

Postal code
13944_91388

Phone
+98 51 3843 6287

Email
alavisadegh157@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Alireza Abdollahimoghaddam

Position
Assistant Professor of Cardiology, University of Science Mashhad Medicine, Mashhad, Iran

Latest degree
Specialist

Other areas of specialty/work
Cardiology

Street address
imamreza hospital

City
Mashhad

Province
Razavi Khorasan

Postal code
13944_91388

Phone
+98 51 3843 6827

Email
alavisadegh157@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Sadegh Alavi

Position
Cardiovascular Resident
Latest degree
Specialist
Other areas of specialty/work
Cardiology
Street address
Ahmadabad St. Shariati Sq. Imam Reza Hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
13944_91388
Phone
+98 51 3843 6287
Email
alavisadegh157@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Sadegh Alavi
Position
Cardiovascular Resident
Latest degree
Specialist
Other areas of specialty/work
Cardiology
Street address
Ahmadabad St. Shariati Sq. Imam Reza Hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
13944_91388
Phone
+98 51 3843 6827
Email
alavisadegh157@gmail.com

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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available