

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 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

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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

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Sadegh Alavi

Position

Cardiovascular Resident

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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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

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

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

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