

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Preventive effect of pretreatment with Intravenous nicorandil VS atorvastatin on contrast-Induced nephropathy in patients with normal renal function undergoing coronary angiography

Protocol summary

Study aim

Preventive effect of pretreatment with Intravenous nicorandil VS atorvastatin on contrast-Induced nephropathy in patients with normal renal function undergoing coronary angiography

Design

In this interventional study, 128 patients who are candidates for coronary angiography will be selected and divided into two groups using block randomization method (n=64 in each group). Proper counseling will be done and a written informed consent will be obtained before starting the treatment regimen.

Settings and conduct

This study will be conducted in the form of double blind in Emam khomeini Hospital of Ardebil, Iran. Patients and clinical evaluators will be unaware of the type of medication they are receiving. The desired variables will be compared in patients undergoing coronary angiography with Nicorandil and atorvastatin.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Coronary angiography, normal renal function. Exclusion criteria: Sensitivity to contrast agent.

Intervention groups

First intervention group: Atorvastatin 80 mg will be used for 3 days before and two days after angiography (Tolidaru Co, Iran). Second intervention group: 10 mg of Nicorandil will be taken daily before 30 minutes to 2 days after angiography (Bluepharma Co, Portugal).

Main outcome variables

Nephropathy due to contrast subjects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150808023559N22**

Registration date: **2020-05-20, 1399/02/31**

Registration timing: **prospective**

Last update: **2020-05-20, 1399/02/31**

Update count: **0**

Registration date

2020-05-20, 1399/02/31

Registrant information

Name

Somaieh Matin

Name of organization / entity

Ardabil University of Medicine Sciences

Country

Iran (Islamic Republic of)

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s.matin@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preventive effect of pretreatment with Intravenous nicorandil VS atorvastatin on contrast-Induced nephropathy in patients with normal renal function

undergoing coronary angiography

Public title

Effect of pretreatment nicorandil VS atorvastatin on contrast-Induced nephropathy in patients with normal renal function

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Coronary angiography Normal renal function

Exclusion criteria:

Sensitivity to contrast agent

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned randomly by blocking in one of the two specified groups and after selecting the envelope for each patient, before starting the treatment regimen envelope will be opened and based on the protocol, one of two methods will be selected.

Blinding (investigator's opinion)

Double blinded

Blinding description

Packages containing the drugs are given to patients in code A and B, and neither patients nor outcome assessors will know the contents of the package.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Ardabil University of Medicine Sciences, Daneshgah street, Ardabil

City

ARDABIL

Province

Ardabil

Postal code

5615783134

Approval date

2020-03-29, 1399/01/10

Ethics committee reference number

lr.arums.rec.1399.013

Health conditions studied

1

Description of health condition studied

Nephropathy

ICD-10 code

N14.1

ICD-10 code description

Nephropathy induced by other drugs, medicaments and biological substances

Primary outcomes

1

Description

Nephropathy due to contrast subjects

Timepoint

24 and 48 hours after angiography

Method of measurement

Measurement of serum creatinine

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Atorvastatin 80 mg will be used for 3 days before and two days after angiography

Category

Diagnosis

2

Description

Control group: 10 mg of Nicorandil will be taken daily before 30 minutes to 2 days after angiography

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Elham Atigi
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Imam Khomeini Hospital, Shahid Jeddi Street, Ardabil
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Ardabil 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
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Full name of responsible person
Elham Atigi

Position
Assistant
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Person responsible for updating data

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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