# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**
En 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**
En 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 Nicurandyl 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)

**Phone**
+98 45 3373 3011

**Email address**
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**
Ir.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
**Street address**
Imam Khomeini Hospital, Shahid Jeddi Street, Ardabil
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elham.atighi@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Ardabil University of Medical Sciences
**Full name of responsible person**
Dr. Shahab Bohloli
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shahab.bohlooli@arums.ac.ir
**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**
Ardabil University of Medical Sciences
**Full name of responsible person**
Elham Atigi
**Position**
Assistant
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Internal Medicine
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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