Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

A clinical trial of the comparison of the effect of oral Nicorandil plus hydration with hydration alone on serum creatinine in high-risk patients after receiving contrast

Protocol summary

Summary

The aim of this study is to investigate the effect of edible Nicorandil (a vasodilator drug used to treat angina) in the prevention of contrast-induced nephropathy. Participated patients in this research candidate for percutaneous coronary intervention that are high-risk in terms of incidence of contrast-induced nephropathy. Patients who have recently received contrast, those with a left ventricular ejection fraction (LVEF) less than 30% (EF<=30%), and those receiving diuretics are eliminated from the study. 128 patients are included randomly in either treatment or control groups. 64 patients receive standard hydration, while the other 64 receive edible nicorandil 2 hours before contrast intake, in addition to the intravenous hydration. Serum creatinine is measured before and 48 hours after injection of contrast in both groups by a laboratory kit.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016033118389N4**
Registration date: **2016-04-25, 1395/02/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-04-25, 1395/02/06

Registrant information

Name

Leili Iranirad

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences and Health Services Vice chancellor for research

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial of the comparison of the effect of oral Nicorandil plus hydration with hydration alone on serum creatinine in high-risk patients after receiving contrast

Public title

Effect of Nicorandil on contrast media-induced acute kidney injury

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria were the existence of at least one risk factor of contrast-induced nephropathy, including 1) Moderate systolic heart failure [30% < (EF) Ejection fraction < 45%] 2) Diabetes 3) Age> 75 years 4) Moderate renal insufficiency (1/5mg/ dL< Cr < 2mg/ dL

5) Hypotension (systolic blood pressure < 90 mm Hg 6) Anemia 7) History of hypertension Exclusion criteria: 1- Pregnancy and lactation 2- Allergy to radiographic contrast 3- Have cardiogenic shock and pulmonary edema during study 4- emergency catheterization 5- Serum creatinine levels> 2 mg/dL and preexisting dialysis 6- Exposure to contrast medium 48 h pre- and post-coronary angiography 7- Receive of diuretics, N-acetylcystein, sodium bicarbonate, Theophylline, Dopamine, Fenoldopam and NSAID'S during the study 8- Needs to continuous hydration therapy (e.g., sepsis) 9- severe heart failure (EF<=30%)

Age
From **20 years** old to **90 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Block Randomization: Block randomization is commonly used in two treatment situations where sample sizes for two treatments are to be equal or approximately equal. The process involves recruiting participants in short blocks and ensuring that half of the participants within each block are allocated to treatment "B" and the other half to "C". Conceptually there are an infinite number of possible block sizes. Suppose we consider blocks of size four. There are six different ways that four patients can be split evenly between two treatments: 1. AABB, 2. ABAB 3. ABBA, 4. BAAB, 5. BABA, 6. BBAA The next step is to select randomly among these six different blocks for each group of four participants that are recruited.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Qom University of Medical Sciences

Street address
Qom University of Medical Sciences and Health Services, Saheli Street, Qom

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Qom

Postal code
3713649373

Approval date
2016-01-04, 1394/10/14

Ethics committee reference number
IR.MUQ.REC.1394.134

Health conditions studied

1

Description of health condition studied
Acute renal failure

ICD-10 code
N14

ICD-10 code description
Drug- and heavy-metal-induced tubulo-interstitial and tubular conditions

Primary outcomes

1

Description
serum creatinine

Timepoint
Before and 48 h after contrast intake

Method of measurement
laboratory Kit (enzymatic method)

Secondary outcomes

empty

Intervention groups

1

Description
Control group: All patients will be received intravenous hydration (2 liters normal saline From 2 h before to 6 h after contrast intake)

Category
Treatment - Drugs

2

Description
Intervention group: All patients will be received Nicorandil 20 mg tablet (two hours before contrast intake) plus intravenous hydration (2 liter Normal saline from 2 h before to 6 h after injection of contrast). Nicorandil, a nicotinamide derivative with the molecular formula C8H9N3O4 ; Causes sustained dilation of both the arterial resistance and conductive vessels. This drug is an anti-angina medication that has the dual properties of nitrate and K+ATP channel agonist.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid- Beheshti hospital
Full name of responsible person
leili Iranirad
Street address
Shahid- Beheshti hospital, Azadegan square, Qom
City
Qom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qom University of Medical Sciences and Health Services Vice chancellor
Full name of responsible person
Hosein Saghafi
Street address
4th Ave, 1.1 Street, Safashahr st./Qom
City
Qom
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qom University of Medical Sciences and Health Services Vice chancellor
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty

Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty