Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

The effect of sodium chloride hydration with and without allopurinol on prevention of contrast-induced nephropathy in high risk patients undergoing coronary angiography

Protocol summary

Summary

Despite the use of low-osmolarity contrast media and prophylactic hydration, contrast-induced nephropathy remains a potentially serious complication of coronary angiography. So this study will be conducted in order to evaluate the effect of allopurinol on prevention of contrast-induced nephropathy in high risk patients undergoing coronary angiography. In this prospective randomized clinical trial, 140 patients with at least one risk factor of nephropathy will be divided to allopurinol plus sodium chloride hydration group (Intervention group; n =70) or to standard intravenous isotonic saline hydration group randomly (Control group; n = 70). Randomization will be performed with block randomization. Serum Creatinine, Blood urea nitrogen (BUN), CRP and Uric Acid will be measured before administration of contrast agent and at 48 h after injection of contrast agent.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072318389N2**
Registration date: **2014-09-24, 1393/07/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-09-24, 1393/07/02

Registrant information

Name

Leili Iranirad

Name of organization / entity

Qom University of Medical Sciences and Health Services

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sodium chloride hydration with and without allopurinol on prevention of contrast-induced nephropathy in high risk patients undergoing coronary angiography

Public title

The effect of Allopurinol on prevention of contrast-induced nephropathy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients, who have at least one of the following risk factors: 1) Heart failure (25%<ejection fraction<40%) 2) diabetes 3) Age >75 years 4) Renal

insufficiency (creatinine 1.5mg/dl) 5) Hypotension (SBP<80 mm Hg for 1 hour) 6) GFR<60/mL/min per 1.73 m2 7) Anemia 8) hypertension 9) Pulmonary edema Exclusion criteria: 1- Pregnancy and lactation 2- Allergy to radiographic contrast 3- Have cardiogenic shock and pulmonary edema during study 4- multiple myeloma, pulmonary ventilation and emergency catheterization 5- Serum creatinine levels< 4 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, Mannitol, Fenoldopam, Metformin and NSAID'S during the study 8- Needs to continuous hydration therapy (e.g., sepsis)

Age
From **18 years** old to **100 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **140**

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 and Health Services

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

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Postal code

Approval date
2014-08-03, 1393/05/12

Ethics committee reference number
muq.rec.1393.18

Health conditions studied

1

Description of health condition studied
Acute renal failure

ICD-10 code
N17

ICD-10 code description
Acute renal impairment

Primary outcomes

1

Description
Nephropathy

Timepoint
Before and 48 h after coronary angiography

Method of measurement
Serum creatinine, blood urea nitrogen (BUN), CRP and uric acid measurement

Secondary outcomes

empty

Intervention groups

1

Description
Interventional group: All patients will be received allopurinol (100mg, TDS) 24 h before administration of contrast agent plus intravenous hydration (1mg /kg/h Normal saline for 12 h pre- and post-contrast)

Category
Treatment - Drugs

2

Description
Control group: All patients will be received intravenous hydration (1 mL/kg/ h) Normal saline for 12 h pre- and post-contrast.

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
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QOM

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qom University of Medical Sciences and Health Services Vice chancellor for research
Full name of responsible person
Hossian Saghafi
Street address
4th Ave, 1.1 Street, Safashahr st./Qom
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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 for research
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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Person responsible for updating data

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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