Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of hydration with normal saline with or without sodium bicarbonate in preventing contrast induced nephropathy in coronary angiography

Protocol summary

Summary

(1) Objectives: Our aim in this study is to evaluate the effect of hydration with normal saline alone or in combination with sodium bicarbonate in preventing contrast induced nephropathy. (2) Design: 350 patients from both genders undergoing coronary angiography in Imam Reza Hospita, Tabriz and Mousavi Hospital, Zanjan after qualifying the inclusion and exclusion criteria and obtaining the informed consent, the patients enter the trial process. (3) Setting and conduct: Patients will randomly assign to receive infusion of normal saline with or without sodium bicarbonate 6 hours before and 6 hours after contrast media injection. Both groups will receive N-acetyl cysteine. Contrast induced nephropathy was defined as an increase of ≥25% or 0.5mg/dl in pre-procedure serum creatinine at 48 h after procedure. (4) Participants including major eligibility criteria: Participants will be selected among the patients undergoing coronary angiography. The key inclusion criteria is elective angiography and the key exclusion criteria are pre-existing end-stage renal disease requiring dialysis; cardiogenic shock; uncontrolled hypertension; recent exposure to radiographic media; serum creatinine level above 4 mg/dl. (5) Intervention:Using normal saline alone or in combination with sodium bicarbonate 6 hours before and 6 hours after injection of contrast media. (6) Main outcome measures: Main outcome measures is contrast induced nephropathy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305205311N2**
Registration date: **2013-05-26, 1392/03/05**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-05-26, 1392/03/05

Registrant information

Name

Bahram Sohrabi

Name of organization / entity

Tabriz University of Medical Sciences and Health Services

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2011-06-22, 1390/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hydration with normal saline with or without sodium bicarbonate in preventing contrast induced nephropathy in coronary angiography

Public title
The effect of normal saline with or without sodium bicarbonate in preventing contrast induced nephropathy in coronary angiography
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: patients undergo elective coronary angiography. Exclusion criteria: pre-existing end-stage renal disease requiring dialysis; cardiogenic shock; uncontrolled hypertension; recent exposure to radiographic media; serum creatinine level above 4 mg/dl
Age
From **18 years** old to **100 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **350**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz university of medical sciences, Daneshgah Square
City
Tabriz
Postal code
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
8816

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
Contrast induced nephropathy
Timepoint
6 hours before and 48 hours after intervention
Method of measurement
measuring serum creatinine

Secondary outcomes

empty

Intervention groups

1

Description
In normal saline group, normal saline will be infused 6 hours before and 6 hours after injection of contrast media.
Category
Treatment - Drugs

2

Description
In normal saline and bicarbonate group, normal saline and sodium bicarbonate will be infused 6 hours before and 6 hours after injection of contrast media.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Madani Heart hospital
Full name of responsible person
Dr. Bahram Sohrabi
Street address
Madani heart hospital, Golbad Ave.,
City
Tabriz

2

Recruitment center

Name of recruitment center
Ayatollah Moosavi educational hospital
Full name of responsible person
Dr. Khalil Mahmoody
Street address
City
Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Seyyed Kazem Shakouri
Street address
Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah square
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tabriz University of Medical Sciences
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

Contact
Name of organization / entity
Tabriz University of Medical Sciences
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Dr. Bahram Sohrabi
Position
Fellowship of intervention/ Associate professor
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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*