

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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 $\geq 25\%$ 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

Iran (Islamic Republic of)

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+98 41 1335 2077

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sohrabib@tbzmed.ac.ir

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
Full name of responsible person
Dr. Bahram Sohrabi
Position
Fellowship of intervention/ Associate professor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

