

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

A Clinical Trial of Comparison between Sodium Bicarbonate and Sodium Chloride Effects for Prevention of Contrast-Induced Acute Kidney Injury Following Diagnostic Coronary Angiography

Protocol summary

Summary

Objectives: The purpose of this study is to compare the incidence of contrast-induced acute kidney injury (CI-AKI) following coronary angiography after administration of sodium bicarbonate and sodium chloride. **Design:** This investigation is randomized and single-blinded. **Setting and conduct:** All patients undergoing coronary angiography are assessed and those who fulfill inclusion criteria are enrolled. One-hundred fifty eight patients are entered into two groups including seventy nine patients. A written informed consent is obtained from all of the patients. And then, all of them will be followed concerning incidence of CI-AKI at 48 hours after coronary angiography. **Participants including major eligibility criteria:** The major inclusion criteria include creatinin level greater than 1.5 mg/dl in men and greater than 1.4 mg/dl in women; creatinin clearance less than 60 ml/min/1.73 m²; older than 18 years; and history of diabetes mellitus for more than one year. The exclusion criteria include cardiogenic shock; heart failure; acute coronary syndrome recently undergone angiography or angioplasty; recent dialysis; single kidney; and any infusion of contrast media such as radiologic interventions. **Intervention:** Group 1 receives sodium chloride 0.9% as 1 mg/kg/h through 12 hours before and after coronary angiography. Group 2 undergoes infusion of sodium bicarbonate (154 mEq in serum DW5%) as 3 mg/kg/h during 1 hour prior to coronary angiography and as 1 mg/kg/h during 6 hours after coronary angiography. **Main outcome measures:** The patients with rising in their creatinin level either up to 0.5 mg/dl or 25% more than basic amount are considered as CI-AKI

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013050813115N1**

Registration date: **2013-05-29, 1392/03/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-05-29, 1392/03/08

Registrant information

Name

Alireza Rai

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

No 1, Vice chancellor for research, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd, Kermanshah, Iran.

Expected recruitment start date

2013-06-01, 1392/03/11

Expected recruitment end date

2014-02-21, 1392/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical Trial of Comparison between Sodium Bicarbonate and Sodium Chloride Effects for Prevention of Contrast-Induced Acute Kidney Injury Following Diagnostic Coronary Angiography

Public title

Evaluation of Sodium Bicarbonate Effect on Contrast-induced Acute Kidney Injury Following Diagnostic Coronary Angiography

Purpose

Prevention

Inclusion/Exclusion criteria

The major inclusion criteria include creatinin level greater than 1.5 mg/dl in men and greater than 1.4 mg/dl in women; creatinin clearance less than 60 ml/min/1.73 m²; older than 18-year-old; and history of diabetes mellitus for more than one year. The exclusion criteria include cardiogenic shock; heart failure; acute coronary syndrome recently undergone angiography or angioplasty; recent dialysis; single kidney; and any infusion of contrast media such as radiologic interventions.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **158**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic's committee of Kermanshah University of Medical Sciences

Street address

No 1, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd, Kermanshah, Iran.

City

Kermanshah

Postal code

Approval date

2013-05-15, 1392/02/25

Ethics committee reference number

25/2/1392

Health conditions studied

1

Description of health condition studied

Ischemic heart diseases

ICD-10 code

I20

ICD-10 code description

Angina pectoris

2

Description of health condition studied

Ischemic heart diseases

ICD-10 code

I21

ICD-10 code description

Acute myocardial Infarction

3

Description of health condition studied

Ischemic heart diseases

ICD-10 code

I24

ICD-10 code description

Other acute ischemic heart diseases

4

Description of health condition studied

Ischemic heart diseases

ICD-10 code

I25

ICD-10 code description

Chronic ischemic heart disease

5

Description of health condition studied

Ischemic heart diseases

ICD-10 code

I22

ICD-10 code description

Subsequent myocardial infarction

Primary outcomes

1

Description

Creatinine

Timepoint

prior angiography and at 48 hours after angiography

Method of measurement

Serum level, mg/dl

Secondary outcomes

1

Description

Creatinin change

Timepoint

Prior angiography and 48 hours after angiography

Method of measurement

serum level, mg/dl

Intervention groups

1

Description

Treatment group: sodium bicarbonate (154 mEq/l in serum DW5%) as 3 mg/kg/h during 1-hour prior to coronary angiography and as 1 mg/kg/h during 6-hour following coronary angiography

Category

Prevention

2

Description

Control group: sodium chloride 0.9% as 1 mg/kg/h through 12 hours before and after coronary angiography

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali hospital

Full name of responsible person

Dr. Alireza Rai

Street address

No 5, Emam Ali hospital, Shahid Beheshti Blvd, Kermanshah, Iran.

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Reza Khoda-Rahmi

Street address

No 1, Vice chancellor for research, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd,

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Kermanshah

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, Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Yousef Rezaei

Position

General Practitioner

Other areas of specialty/work

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Other areas of specialty/work
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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