Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative Study of Effect of One Third, Two Third and Normal Saline Serum on Prevention of Contrast Induced Nephropathy in Patients Undergoing Cardiac Angiography.

Protocol summary

Summary

In this randomized clinical trial study, we intend to compare effect of one third, two third and normal saline serum on prevention of contrast induced nephropathy in patients undergoing cardiac angiography. Among the patients(aged 15 to 85 years old) undergoing cardiac angiography, the patients who had glomerular filtration of below 60 or had serum creatinine of above or equal to 1.5 after performing routine tests in angiography ward of which part is serum creatinine were included in the study. One third, two third or normal saline serum plus sodium bicarbonate will be prescribed randomly, one hour before angiography, during angiography and up to 6 hours after it with speed of 1 cc for each kg per hour. Three and five days after angiography, serum creatinine will be tested and contrast induced nephropathy will be diagnosed based on increase of creatinine by 25% of basic limit or increase by more than 0.5 mg per decimeter . Now, the number of contrast induced nephropathy cases will be compared in two groups of samples (two groups each containing 50 members) and will be statistically studied. In this study, Visipaque contract and at most 100 cc will be used and patients with severe valve diseases will not be included in the study due to their need for more contrast.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071413987N1**
Registration date: **2013-11-01, 1392/08/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-11-01, 1392/08/10

Registrant information

Name

Mohammad Kazem Karimi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

kzk_137253@yahoo.com

Recruitment status

Recruitment complete

Funding source

Kermanshah University Of Medical Scienses, Vice chancellor for research

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study of Effect of One Third, Two Third and Normal Saline Serum on Prevention of Contrast Induced Nephropathy in Patients Undergoing Cardiac Angiography.

Public title

Studying Effect of One Third, Two Third and Normal Saline Serum on Contrast Induced Nephropathy.

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:Glomerular Filtration Rate(GFR) of below 60 or serum creatinine of above or equal to 1.5 mg/dl. Exclusion criteria:Severe valve diseases and age less than 15 and more than 85 years.
Age
From **15 years** old to **85 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
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
Ethics committee of Kermanshah University of Medical Sciences
Street address
Building number two, Shahid Beheshti Blvd. Kermanshah
City
Kermanshah
Postal code
6714673159
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
53925

Health conditions studied

1

Description of health condition studied
Contrast Induced Nephropathy
ICD-10 code
T65.6
ICD-10 code description
Paints and dyes, not elsewhere classified

Primary outcomes

1

Description
creatinine
Timepoint
On admission,3 and 5 days after angiography
Method of measurement
Based on milligram per deciliter and by automated analyzer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention1:A group of patients will be given sodium bicarbonate plus one third and two third serum randomly, with speed of 1 cc for each kg per hour one hour before, , during and up to 6 hours after angiography. Sodium Bicarbonate 7.5%, each 100 cc contains; 7.5 gram sodium bicarbonate, Iran-Samen Pharmaceutical Company. One third and two third serum, each 100 cc contains; 3.33 gram dextrose and 0.3 gram sodium chloride, Iran Pharmaceutical Products Company.
Category
Prevention

2

Description
Intervention2: Second group of patients will be given sodium bicarbonate plus normal saline serum randomly, with speed of 1 cc for each kg per hour one hour before, , during and up to 6 hours after angiography. Normal saline 9%: each 100 cc contains 9 gram sodium chloride,Iran Pharmaceutical Products Company.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Heart Centre
Full name of responsible person
Mohammad Kazem Karimi
Street address
Shahid Beheshti Blvd. kermanshah
City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences,vice chancellor for research

Full name of responsible person
Kermanshah University of Medical Sciences,vice chancellor for research

Street address
Medical College, Shahid Shiroodi Blvd. University Street,Kermanshah

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kermanshah University of Medical Sciences,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

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Mohammad Kazem Karimi

Position
Cardiology resident

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