

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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kzk_137253@yahoo.com

Recruitment status

Recruitment complete

Funding source

Kermanshah University Of Medical Sciences, 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
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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

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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