Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of normal saline, ringer lactate and sodium bicarbonate for prevention of contrast induced nephropathy in the patients who underwent coronary angiography in Shiraz

Protocol summary

Summary

The aim of this study is to compare the efficacy of normal saline, Ringer lactate and sodium bicarbonate in preventing contrast induced nephropathy in patients undergoing coronary angiography. This is a double-blind, unicenter, non-placebo-controlled study in 300 patients over 18 years old who have indication for coronary angiography. Patients with hemodynamic instability, severe heart failure, pulmonary edema, electrolyte and acid-base disorders and patients under dialysis are not included. Furthermore, Patients experiencing any unwanted complication during or after angiography are excluded from the study. Patients are divided into 3 groups using simple randomization method. The first group receives normal saline 0.9% while the second group and the third one receive Ringer lactate and sodium bicarbonate solution respectively as intravenous injection. Fluids are administered by 3 ml/kg one hour before angiography and 1 ml/kg/hour for 6 hours after the angiography. All patients receive N-acetylcysteine tablet orally twice a day from 1 day before to 1 day after angiography. Metformin and diuretics administration is stopped before the study. Creatinine increase greater than 0.3 mg/dl or more than 25% compared to serum baseline is valuable. Tests for potassium, sodium, creatinine, blood urea nitrogen, and urine pH and estimated glomerular filtration rate are evaluated before and after angiography and the consequences in terms of prevention of kidney disorders are observed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080323483N1**
Registration date: **2016-10-21, 1395/07/30**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-10-21, 1395/07/30

Registrant information

Name

Zahra Salmanpour

Name of organization / entity

Shiraz University of Medical Sciencies

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 5610

Email address

salmanpur@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

governmental, Sums research center

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of normal saline, ringer lactate and sodium bicarbonate for prevention of contrast induced nephropathy in the patients who underwent coronary angiography in Shiraz

Public title

The comparison of different types of fluid therapy in prevention of contrast induced renal malfunction in coronary angiography

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients over 18 y/o who have indications for coronary angiography and angioplasty are included. However, patients with hemodynamic instability, severe cardiac failure or pulmonary edema, under dialysis, under medications potentially affecting kidney function or with electrolyte and acid-base disturbances are not included. Exclusion criteria: patients with undesired complications such as arterial dissection during angiography or angioplasty are excluded from the study.

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: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study, both physician and patients were unaware of the nature of the therapy; therefore, it is considered as a double blind study. randomization method: for each patient, a code will be generated by using random-numbers table.If the ones of the code is (1,2,3) the patient will be placed in the first group (normal saline). If the ones of the code is (4,5,6) or (7,8,9) the patient will be categorized in the second (ringer lactate) and third group (sodium bicarbonate) respectively. In addition the codes with ones equal to zero will be deleted.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand Blvd. Shiraz

City

Shiraz

Postal code

Approval date

2015-07-12, 1394/04/21

Ethics committee reference number

IR.SUMS.REC.1394.71

Health conditions studied

1

Description of health condition studied

contrast induced nephropathy

ICD-10 code

N14.1

ICD-10 code description

Nephropathy induced by other drugs, medicaments and biological substances

Primary outcomes

1

Description

Creatinine

Timepoint

before and 48 hours after intervention

Method of measurement

Jaffe with adsorbent (picrate) method

2

Description

BUN

Timepoint

before and 48 hours after intervention

Method of measurement

urease/GLDH method

3

Description

urine PH

Timepoint

before and 6 hours after intervention

Method of measurement

PH meter sticks

4

Description

estimated GFR (eGFR)

Timepoint

before and 48 hours after intervention

Method of measurement

MDRD equation

Secondary outcomes

1

Description
Sodium and Potassium (Na and K)
Timepoint
before and 48 hours after intervention
Method of measurement
flame photometry method

Intervention groups

1

Description
Intervention 1: In this group, the patients receive intravenous normal saline (0.9%) at a rate of 3 ml/kg one hour before angiography and 1 ml/kg per hour for 6 hours after angiography.
Category
Prevention

2

Description
Intervention 2: In this group, the patients receive intravenous ringer lactate at rate of 3 ml/kg one hour before angiography and 1 ml/kg per hour for 6 hours after angiography.
Category
Prevention

3

Description
Intervention 3: In this group, the patients receive intravenous sodium bicarbonate (850 ml DW 5% plus 150 mEq sodium bicarbonate) at a rate of 3 ml/kg one hour before angiography and 1 ml/kg per hour for 6 hours after angiography.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Faghihi hospital
Full name of responsible person
Street address
Zand Blvd. Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
vice chancellor for research, Shiraz University of Medical Sciences
Full name of responsible person
Dr.S.B. Hashemi
Street address
Shiraz University of Medical Sciences, Zand Blvd.
City
Shiraz
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, Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Dr. M. Pakfetrat
Position
nephrologist
Other areas of specialty/work
Street address
Internal medicine department, Namazi hospital, Namazi square
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Shiraz
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Phone
00
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Email
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
Dr. M. Pakfetrat
Position
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Other areas of specialty/work
Street address

Internal medicine department, Namazi hospital, Namazi sq.

City

Shiraz

Postal code

Phone

+98 71 3612 5610

Fax

Email

pakfetratm@sums.ac.ir

Web page address

Person responsible for updating data

Contact

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