Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

A clinical trial of the comparison of the effect of drug Na/K citrate per os plus hydration with hydration alone on serum creatinine in high-risk patients after receiving contrast

Protocol summary

Summary

The aim of this study is investigation the effect of edible sodium potassium citrate (urine-alkalization agent utilized in treatment of uric acid kidney stones) for prevention of contrast-induced nephropathy. Patients who are participated in this research, are considered as the high-risk patients in terms of incidence of contrast-induced nephropathy for percutaneous coronary intervention. Patients who have recently received contrast, those with a left ventricular ejection fraction (LVEF) less than 30% (EF<=30%) , and those receiving diuretics are not taking part in this study. 400 patients are included randomly in either treatment or control groups. 200 patients will receive standard hydration, while the other 200 will receive edible sodium potassium citrate 2 hours before and 4 hours following the contrast intake, in addition to the intravenous hydration (urine alkalinity by Na/K citrate is investigated by urine dipstick 1 hour after oral intake) . In both groups, Serum creatinine level will be measured before and 48 hours after injection the contrast media.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015011618389N3**
Registration date: **2015-04-30, 1394/02/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-04-30, 1394/02/10

Registrant information

Name

Leili Iranirad

Name of organization / entity

Qom University of Medical Sciences and Health Services

Country

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Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences and Health Services Vice chancellor for research

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2016-01-22, 1394/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial of the comparison of the effect of drug Na/K citrate per os plus hydration with hydration alone on serum creatinine in high-risk patients after receiving contrast

Public title

Effect of Na/K citrate on contrast media-induced acute kidney injury

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria are the existence of at least one risk factor of contrast-induced nephropathy, namely: 1- Moderate systolic heart failure [(EF) Ejection Fraction between 30-45%]2- Diabetes mellitus 3- Older than 75 year-old 4- Moderate renal insufficiency (serum creatinine level between 1/5-2 mg/dl) 5- Hypotension (systolic blood pressure less than 90 mm Hg 6- Anaemia 7- History of hypertension. Exclusion criteria; 1- pregnancy and lactation 2- History of allergic reaction to contrast media 3- Occurrence of cardiogenic shock and pulmonary edema during study 4-Urgent catheterization 5- Serum creatinine level higher than 2 mg/dl and previous history of dialysis 6- Receiving contrast medium 48 h before and after the intervention 7- Receiving diuretics, N-acetylcystein, sodium bicarbonate, theophylline, dopamine, mannitol, fenoldopam, metformin and NSAID'S during the study 8- Requiring to continue hydration therapy (e.g., sepsis condition) 9- Severe heart failure [left ventricular ejection fraction (LVEF) less than 30%]

Age

From **20 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **400**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Block Randomization: Block randomization is commonly used in two treatment situations where sample sizes for two treatments are to be equal or approximately equal. The process involves recruiting participants in short blocks and ensuring that half of the participants within each block are allocated to treatment "B" and the other half to "C". Conceptually there are an infinite number of possible block sizes. Suppose we consider blocks of size four. There are six different ways that four patients can be split evenly between two treatments: 1. AABB, 2. ABAB 3. ABBA, 4. BAAB, 5. BABA, 6. BBAA The next step is to select randomly among these six different blocks for each group of four participants that are recruited.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Research Committee of Qom University of Medical Sciences

Street address

Qom University of Medical Sciences and Health Services, Saheli Street, Qom

City

Qom

Postal code

Approval date

2015-01-04, 1393/10/14

Ethics committee reference number

MUQ.REC 1393.99

Health conditions studied

1

Description of health condition studied

Acute renal failure

ICD-10 code

N17

ICD-10 code description

Acute renal impairment

Primary outcomes

1

Description

serum creatinine

Timepoint

Before and 48 h after contrast intake

Method of measurement

laboratory Kit (enzymatic method)

2

Description

Urine PH

Timepoint

Before and 1 hour after citrate intake

Method of measurement

Urine dipstick

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: all of the patients will receive Na/K citrate (one hour before and four hours after contrast intake) in addition to intravenous hydration (2 litter normal saline from 2 h before to 6 h after injection of contrast media). Potassium citrate is a potassium salt of

citric acid with the molecular formula C6H5K3O7. Sodium citrate has the chemical formula of Na3C6H5O7. The combination formula is sodium –potassium citrate, a white odorless crystalline powder with a saline taste. It rapidly absorbs when given by mouth and leads to urine alkalization. It is widely administered in urinary calculi (kidney stones) treatment. The drug applied in this research (trade name Na/K Citrate) is made in Iran (Sepidaj chemical company).

Category

Treatment - Drugs

2

Description

Control group: All patients will receive intravenous hydration (2 litter of normal saline From 2 h before until 6 h after the contrast intake)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid- Beheshti hospital

Full name of responsible person

leili Iranirad

Street address

Shahid- Beheshti hospital, Azadegan square, Qom

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qom University of Medical Sciences and Health Services Vice chancellor

Full name of responsible person

Hosein Saghafi

Street address

4th Ave, 1.1 Street, Safashahr st./Qom

City

Qom

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qom University of Medical Sciences and Health Services Vice chancellor

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

Qom University of Medical Sciences and Health Services

Full name of responsible person

Leili Iranirad

Position

Assistant professor of Cardiology

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