

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of three protective regimens for preventing contrast-induced nephropathy in high risk patients undergoing coronary angiography

Protocol summary

Summary

Despite the use of low-osmolality contrast media and prophylactic hydration, contrast-induced nephropathy (CIN) remains an unsolved problem of the contemporary medical practice. So this study will be conducted in order to comparison of 3 protective regimens for preventing contrast-induced nephropathy in high risk patients undergoing coronary angiography in Shahid- Beheshti hospital Qom, 2012. In this work, 147 patients, who have at least one of the following risk factors: age >65 years, diabetes mellitus, heart failure (25%> ejection fraction >40%), renal insufficiency (creatinine³1.5mg/dl), control hypertension (BP<160/100 mmHg) or recent use of NSAID'S, ACE inhibitor and amino glycosides drugs will be studied. The patients will be randomized 1 of 3 prophylactic regimens: 49 patients will be assigned to infusion of sodium bicarbonate solution, 49 patients to oral NAC plus hydration with normal saline, 49 patients to standard hydration with normal saline (control group). Serum creatinine and blood urea nitrogen (BUN) levels will be measured in the morning on the first day before coronary angiography (day 1) and in the morning on second day after the procedure. PH urine level will be measured in the morning on the day before and after coronary angiography

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202062560N6**

Registration date: **2012-02-28, 1390/12/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-02-28, 1390/12/09

Registrant information

Name

Mohammad reza Yeganehkhah

Name of organization / entity

Qom University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 21 6630 4368

Email address

yeganehkhah@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Qom University of Medical Sciences

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2012-08-22, 1391/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of three protective regimens for preventing contrast-induced nephropathy in high risk patients undergoing coronary angiography

Public title

Comparison of 3 Protective regimens for preventing contrast-induced nephropathy in high risk patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients, who have at least one of the

following risk factors: 1) Age>65 years, 2) Diabetes mellitus, 3) Heart failure (25%>ejection fraction>40%), 4) Renal insufficiency (creatinine³1.5mg/dl), 5) Control hypertension (systolic and diastolic blood pressure <160 mm Hg and < 100 mm Hg, respectively), 6) Recent use of NSAID'S, ACE inhibitor and amino glycosides drugs. Exclusion criteria : 1) Pregnancy & lactation, 2) Allergy to radiographic contrast, 3) Have of cardiogenic shock, pulmonary edema, multiple myeloma, pulmonary ventilation and emergency catheterization 4) Serum creatinine levels< 4 mg/dL and preexisting dialysis 5) Exposure to contrast medium within the preceding 48 hours of the study, 6) Receive of diuretics, N-acetylcystein, sodium bicarbonate, theophylline, dopamine, mannitol, fenoldopam, metformin and NSAID'S during the study period. 7) Need for continuous hydration therapy (e.g., sepsis), 8) Uncontrolled hypertension (systolic and diastolic blood pressure >160 mm Hg and >100 mm Hg, respectively)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **147**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qom University of Medical Sciences and Health Services

Street address

Qom University of Medical Sciences and Health Services, Saheli st.

City

Qom

Postal code

Approval date

2012-02-02, 1390/11/13

Ethics committee reference number

18958/34/ت

Health conditions studied

1

Description of health condition studied

Contrast-induced nephropathy

ICD-10 code

N14.3

ICD-10 code description

Nephropathy induced by heavy metals

Primary outcomes

1

Description

Decrease of contrast-Induced nephropathy

Timepoint

Serum creatinine and blood urea nitrogen (BUN) levels will be measured in the morning on the first day before coronary angiography (day 1) and in the morning on second day after the procedure. PH urine level will be measured in the morning on the day before and after coronary angiography.

Method of measurement

Serum creatinine, blood urea nitrogen (BUN) and PH urine levels will be measured, and creatinine clearance will be calculated according to the Cockcroft-Gault equation.

Secondary outcomes

empty

Intervention groups

1

Description

(1) The sodium bicarbonate solution will be prepared by adding 150 mL of 1000-mEq/L sodium bicarbonate to 850 mL of sodium chloride. Patients will receive the same dose of sodium bicarbonate solution (3mL/ kg/ h) for 1 hour before contrast media, followe by an infusion of 1 mL/kg per hour for 6 hours after the procedure.

Category

Treatment - Drugs

2

Description

(2) All patients will be received the same dose of sodium chloride (1 mL/kg/ h upper limit 100 mL/h) for 12 hours before and 12 hours after the procedure. The study drug (acetylcysteine 600 mg) will be administered orally twice daily for two doses before the procedure and two doses after the procedure

Category

Treatment - Drugs

3

Description

(3) All patients will be received the same dose of sodium chloride (1 mL/kg/h upper limit 100 mL/h) for 12 hours before and 12 hours after the procedure.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid- Beheshti hospital

Full name of responsible person

Street address

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qom University of Medical Sciences and Health Services

Full name of responsible person

Koohpaei Ali Reza

Street address

Qom University of Medical Sciences and Health Services, Saheli st.

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

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

Mohammad Reza Yeganeh khah

Position

MSc in Community Health Nursing

Other areas of specialty/work

Street address

No. 12, 2 Senobar lane., Sepideh Ave., Bahrami St., Saeedi highway

City

Tehran

Postal code

Phone

+98 21 6630 4368

Fax

Email

yeganehkhah@muq.ac.ir , yeganeh3603@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qom University of Medical Sciences and Health Services

Full name of responsible person

Mohammad Reza Yeganeh khah

Position

MSc in Community Health Nursing

Other areas of specialty/work

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Phone

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Fax

Email

yeganehkhah@muq.ac.ir , yeganeh3603@yahoo.com

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