

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

prevention of contrast induced nephropathy(CIN) in pateints with some degree of chronic kidney disease (CKD) undergoing coronary angioplasty/graphy with sodium potassium citrate solution(shohl's solution)

Protocol summary

Summary

objective: testing the hypothesis that alkalinization of urine, using sodium potassium citrate, reduces the risk of contrast nephropathy in patients with some degree of CKD during coronary angioplasty/graphy. Method: randomised (using block randomization method) double blind palacebo-controlled trial single center 3th phase of trial. Study population: all adult patients (more than 18 years old) candidate for elective coronary angioplasty/graphy and have CKD (at least stage 2). Exclusion criteria: ESRD; AKI; exposure to contrast media within last 10 days; GFR more than 90 cc per min; pregnancy; drug history of (NAC or NaHco3) 48 hours before intervention. Sample size: 190 patients. All patients will receive 1 ml/kg/h 0.9% sodium chloride for 12 h before and after the procedure. Intervention group will receive the Na/K citrate solution, a dose of 7.5 g of granules diluted in 200 mL of water, before and after the procedure. placebo group will receive twice 200 mL of water instead. Method of blindness: Both drug and placebo are liquid and bottled in 200 cc black bottles and will be given to patients by a nurse who is unaware of intervention assignment. first outcome measure of the study is development of CIN. Additional end points are: adverse clinical events including in-hospital mortality, need for dialysis, need for readmitting due to CIN and mean peak increase in serum creatinine.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015050322065N1**
Registration date: **2015-08-13, 1394/05/22**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-13, 1394/05/22

Registrant information

Name

Alireza Sattari

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences,
medical school

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

the project will be funded by vice chancellor of research,
Ahvaz University of Medical Sciences

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

prevention of contrast induced nephropathy(CIN) in
pateints with some degree of chronic kidney disease
(CKD) undergoing coronary angioplasty/graphy with

sodium potassium citrate solution(shohl's solution)

Public title

prevention of kidney injury caused by contrast media during angioplasty/graphy by adminstration of sodium potassium citrate solution

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all adult patients (more than 18 years old) candidate for elective coronary angioplasty/graphy and have CKD (at least stage 2) Exclusion criteria: ESRD (GFR less than 15cc per min); AKI; exposure to contrast within last 10 days; history of sensitivity to contrast media; pulmonary edema; multiple myeloma; history of (diarrhea, vomiting, dehydration status, bleeding); pregnancy; drug history of (NAC, teofiline, dopamine, fenoldopam, manitol and NaHCO3) 48 hours before intervention; consumption of nephrotoxic drugs 48 hours before till one week following the intervention; electrolytes disturbance (i.e hyperkalemia or alkalosis) or GFR more than 90 cc per min; refusal to participate

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **190**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Hwy, Ahvaz, Khuzestan, Iran

City

Ahvaz

Postal code

61357-15794

Approval date

2014-11-15, 1393/08/24

Ethics committee reference number

ajums.REC.1393.260

Health conditions studied

1

Description of health condition studied

contrast induced nephropathy

ICD-10 code

N 14

ICD-10 code description

Drug- and heavy-metal-induced tubulo-interstitial and tubular conditions

Primary outcomes

1

Description

Contrast induced nephropathy defined as (an absolute increase of at least 0.5 mg/dl or a relative increase $\geq 25\%$ or more from baseline serum Cr or a reduction in GFR at least 25% or more from baseline value.

Timepoint

Serum creatinine concentration will be checked at the time of admission and and on days 2,5 after the expose to contrast

Method of measurement

Serum creatinine concentration will be assessed using biochemistry method

Secondary outcomes

1

Description

in-hospital death or mortality following CIN development

Timepoint

in-hospital follow up and post-discharge follow up based on patern of serum cratinine change and ultimately one month after CIN development

Method of measurement

via visiting patient

2

Description

need for dialysis or hemofiltration following CIN

Timepoint

will be evaluated based on the patern of serum cratinine changes following CIN development

Method of measurement

via visiting patient and assessment of patients serum cratinine and electrolytes status

3

Description

need for readmission following CIN development

Timepoint

based on the patterns of serum cratinine changes following CIN development

Method of measurement

via visiting patient and assessment of patients serum cratinine and electrolytes status

4

Description

mean peak increase in serum cratinine following CIN development

Timepoint

via assessing serum cratinine on days 2 and 5 following CIN development

Method of measurement

via assessing serum cratinine using biochemical assays

Intervention groups

1

Description

patients in intervention arm of the study will receive 1 ml/kg/h 0.9% sodium chloride 12 h before and after the procedure. in this group patients will receive 7.5 g of sodium potassium citrate granules (Uralyt U, Germany) diluted in 200 mL of water two times before and after the operation.

Category

Prevention

2

Description

patients in placebo arm of the study will receive 1 ml/kg/h 0.9% sodium chloride 12 h before and after the procedure. in this group patients will receive 200 mL of water ,as placebo, two times before and after the operation.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Emam Khomeini hospital, coronary care unit(CCU)

Full name of responsible person

Alireza Sattari, medical student (intern)

Street address

coronary care unit(ccu1 and 2 and 3), Emam khomeini hospital, Azadegan street(formerly 24-Metri), Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Nader saki (chair man of Research deputy of Ahvaz, Jundishapur University of Medical science)

Street address

Vice chancellor for research, Jundishapur University of Medical science, Golestan Hwy, Ahvaz

City

Ahvaz

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, Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences, medical school, Golestan hospital, internal medicine

Full name of responsible person

Dr Ali Ghorbani

Position

internist, nephrologist (associate professor)

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