Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

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Alireza Sattari
Name of organization / entity
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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 □□□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 paterns 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 biochemichal 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 medici
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