Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing preventive effect of ascorbic acid versus isotonic sodium bicarbonate against acute kidney injury after adults on-pump cardiac surgery

Protocol summary

Summary

Objective: To compare the effect of ascorbic acid versus isotonic bicarbonate in preventing acute post operative renal failure in cardiac surgery Design: Prospective randomized clinical trial Setting and conduct: One hundred and fifty adult patients candidate for elective cardiac surgery, randomly will be allocated in three ascorbic acid, bicarbonate and placebo groups (N=50). Preoperative plasma creatinine concentration will be measured in all patients and glomerular filtration rate (GFR) will be calculated. Anesthesia induction and maintenance will be done using intravenous midazolam, fentanyl and cisatracurium. After anesthesia induction, one liter of normal saline will be administrated during next two hours. This serum will contain ascorbic acid (200 mg), isotonic bicarbonate (75 ml of bicarbonate 8.4%) or will be pure normal saline, respectively. Plasma creatinine will be measured in second and fifth post operative days and GFR will be calculated. At the end, the plasma creatinine and GFR changes will be compared between three groups. Inclusion criteria: All patients above 18 years old who are candidate for elective cardiac surgery Exclusion Criteria: Age below 18 Years Old; Urgent Surgery; Plasma creatinine higher than 2 mg/dl; GFR lower than 50 ml/min; Insulin depended diabetes mellitus; Radio contrast exposure during last weak; left ventricle ejection fraction below 30% Intervention: Starting infusion of one liter of normal saline that contain ascorbic acid (500 mg) or is isotonic bicarbonate solution after induction of anesthesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409091127N3**

Registration date: **2015-03-10, 1393/12/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-10, 1393/12/19

Registrant information

Name

Eissa Bilehjani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-11-01, 1393/08/10

Expected recruitment end date

2015-09-01, 1394/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing preventive effect of ascorbic acid versus isotonic sodium bicarbonate against acute kidney injury after adults on-pump cardiac surgery

Public title
Comparing preventive effect of ascorbic acid versus isotonic sodium bicarbonate against acute kidney injury after adults on-pump cardiac surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Patients above 18 years old who are candidate for elective cardiac surgery Exclusion Criteria: Urgent Surgery; Plasma creatinine concentration above 2 mg/dl; GFR lower than 50 ml/min; Insulin depended diabetes mellitus; Radio contrast exposure during last weak; left ventricle ejection fraction below 30%
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Using stratified permuted block randomization method, 150 patients will be allocated in three ascorbic acid, bicarbonate and placebo groups (N=50).

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
Daneshgah Street, Tabriz University of Medical Sciences Tabriz, Vice Chancellor for Research of Tabriz University of Medical Sciences
City
Tabriz
Postal code
Approval date
2014-02-12, 1392/11/23
Ethics committee reference number
93185

Health conditions studied

1

Description of health condition studied
Acute Post Operative Renal Failure
ICD-10 code
N17.9
ICD-10 code description
Acute Renal Failure, Unspecified

Primary outcomes

1

Description
Acute renal failure
Timepoint
At second and fifth postoperative days
Method of measurement
Monitoring the increase in plasma creatinine more than 0.5mg/dl or decrease in GFR more than 25 percent up to fifth postoperative day comparing to preoperative values

Secondary outcomes

1

Description
Plasma Creatinine Concentration and Glomerular Filtration Rate
Timepoint
At Preoperative, Second and Fifth Post Operative Days
Method of measurement
Plasma Creatinine Concentration and Glomerular Filtration Rate measurement

Intervention groups

1

Description
Intervention group1: Infusion of one liter of normal saline that will contain ascorbic acid (500 mg) during first two hours of anesthesia
Category
Treatment - Drugs

2

Description
Intervention group 2: Infusion of one liter of normal saline that will contain 75 ml of sodium bicarbonate 8.4% during first two hours of anesthesia
Category
Treatment - Drugs

3

Description
Placebo group: Infusion of one liter of pour normal saline during first two hours of anesthesia

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Madani Heart Hospital
Full name of responsible person
Eissa Bilehjani
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Madani Heart Center, Daneshgah Street, Tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Reza Rashidi
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Tabriz University of Medical Sciences, Daneshgah Street, Tabriz
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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 of Tabriz 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

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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