

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

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

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### 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 week; 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.

Last update:

Update count: **0**

#### Registration date

2015-03-10, 1393/12/19

#### Registrant information

##### Name

Eissa Bilehjani

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3329 6124

##### Email address

bilehjani@tbzmed.ac.ir

#### 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

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201409091127N3**

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

## 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

**Street address**

Madani Heart Center, Daneshgah Street, Tabriz

**City**

Tabriz

## 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

**Street address**

Tabriz University of Medical Sciences, Daneshgah Street, Tabriz

**City**

Tabriz

**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

### Contact

**Name of organization / entity**

Medicine faculty, Tabriz University of Medical Sciences

**Full name of responsible person**

Hassan Soleiman Pour

**Position**

Vice Chancellor for research of Tabriz Medicine

faculty

**Other areas of specialty/work**

**Street address**

Tabriz Medicine faculty, Daneshgah Street, Tabriz

**City**

Tabriz

**Postal code**

**Phone**

+98 41 3336 4667

**Fax**

**Email**

soleimanpourh@tbzmed.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Solmaz Fakhari

**Position**

Assistant Professor in Anesthesiology

**Other areas of specialty/work**

**Street address**

Madani Hospital, Daneshgah Street, Tabriz

**City**

Tabriz

**Postal code**

**Phone**

+98 41 3337 3950

**Fax**

**Email**

solmaz\_fakhari@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Eissa Bilehjani

**Position**

Assistant Professor in Anesthesiology

**Other areas of specialty/work**

**Street address**

Madani Hospital, Daneshgah Street, Tabriz

**City**

Tabriz

**Postal code**

**Phone**

+98 41 3337 3950

**Fax**

+98 41 3337 3950

**Email**

bilehjani@tbzmed.ac.ir; isa\_bilehjani@yahoo.com;

isadavod@gmail.com

**Web page address**

## **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*