Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Determination of the rate of acute kidney injury incidence, following fluid resuscitation with isotonic saline compared to Ringer lactate in patients undergoing on-pump coronary bypass, hospitalized in the intensive care unit (ICU)

Protocol summary

Summary

Objectives: Determination of the rate of acute kidney injury incidence, following fluid resuscitation with isotonic saline compared to Ringer lactate in patients undergoing off-pump coronary bypass, hospitalized in the intensive care unit (ICU). Design: Randomized clinical trial, single blind, Target sample size: 966 people. Inclusion criterion to study: patients after undergoing elective off-pump coronary bypass. Exclusion criteria from study: Emergency surgical operation; Previous history of cardiac surgery; American Society of Anesthesiologists Class (ASA) more than 4; Previous history of kidney diseases; Diabetic nephropathy; Preoperative serum creatinine level more than 1.3; Preoperative glomerular filtration rate (GFR) less than 75%, 8) preoperative ejection fraction (EF) less than 30%; Drainage more than the volume during the surgery; Use of a balloon pump during or after the surgery; Prolonged recurrent ventricular fibrillation (VF) during the surgery; High dose inotrope (inotrope 2) during the surgery; Lack of patient's consent to participate in the study. Patients are also excluded during the study period if hyperchloremia (CL more than 110) occurs in the ICU, Various complications might occur (hemorrhage, drainage, cardiac arrest, prolonged hemodynamic instability, and neurological complications of CVA), which result in the exclusion of patients from the study. Control group: Isotonic saline 0.9% containing 154 mEq chlorine ion, 40 CC/kg at 24 hours after surgery Intervention group: Ringer lactate containing 109 mEq chlorine ion, 40 CC/kg at 24 hours after surgery. Primary outcome: Arterial blood gases, Before and at the first 24 hours after intervention, every 4 hours, By Blood test; Blood urea nitrogen, Before and after intervention, daily by blood test, venous blood samples from the arm; Blood creatinine level, daily by blood test in jaffe method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041813159N2**
Registration date: **2014-06-15, 1393/03/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-06-15, 1393/03/25

Registrant information

Name
Shima Sheybani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3764 7230
Email address
sheybanish@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Mashhad University of Medical Sciences

Expected recruitment start date

2014-06-28, 1393/04/07

Expected recruitment end date

2015-05-28, 1394/03/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Determination of the rate of acute kidney injury incidence, following fluid resuscitation with isotonic saline compared to Ringer lactate in patients undergoing on-pump coronary bypass, hospitalized in the intensive care unit (ICU)

Public title
Diagnosis of acute kidney injury in patients undergoing on-pump coronary artery bypass

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria: patients after undergoing elective on-pump coronary bypass. Exclusion criteria: Emergency surgical operation; Previous history of cardiac surgery; American Society of Anesthesiologists Class (ASA) more than 4; Previous history of kidney diseases; Diabetic nephropathy; Preoperative serum creatinine level more than 1.3; Preoperative glomerular filtration rate (GFR) less than 75%; preoperative ejection fraction (EF) less than 30%; Drainage more than the volume during the surgery; Use of a balloon pump during or after the surgery; Prolonged recurrent ventricular fibrillation (VF) during the surgery; High dose inotrope (inotrope 2) during the surgery; Lack of patient’s consent to participate in the study. Patients are also excluded during the study period if hyperchloremia (CL more than 110) occurs in the ICU, Various complications might occur (hemorrhage, drainage, cardiac arrest, prolonged hemodynamic instability, and neurological complications of CVA), which result in the exclusion of patients from the study.

Age
From **20 years** old to **75 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **966**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Male and female subjects, undergoing coronary artery bypass (off-pump) surgery for the first time, were randomly allocated to two groups (block method). Researchers are unaware.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street, Mashhad

City
Mashhad

Postal code

Approval date
2013-11-23, 1392/09/02

Ethics committee reference number
920804

Health conditions studied

1

Description of health condition studied
Kidney injury

ICD-10 code
N18.9

ICD-10 code description
Chronic kidney disease, unspecified

Primary outcomes

1

Description
Arterial blood gases

Timepoint
Before intervention and at the first 24 hours after intervention, every 4 hours

Method of measurement
Blood test

2

Description
Blood urea nitrogen

Timepoint
Before and after intervention, daily

Method of measurement
Blood test, venous blood samples from the arm

3

Description
Blood creatinine level

Timepoint
After intervention, daily

Method of measurement
Blood test in jaffe method

4

Description
Sodium
Timepoint
Before intervention and at the first 24 hours after intervention, every 4 hours
Method of measurement
Blood test

5

Description
Lactate
Timepoint
Before and after intervention, daily
Method of measurement
Blood test

Secondary outcomes

1

Description
Chlorine
Timepoint
Before surgery and after surgery Daily
Method of measurement
Blood test

Intervention groups

1

Description
Control group: Isotonic saline 0.9% containing 154 mEq chlorine ion, 40 CC/kg at 24 hours after surgery
Category
Diagnosis

2

Description
Intervention group: : Ringer lactate containing 109 mEq chlorine ion, 40 CC/kg at 24 hours after surgery.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Siamak Boustan
Street address
Imam Reza Hospital, Imam Reza Square, Mashhad
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street, Mashhad
City
Mashhad
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, Mashhad 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
Mashhad University of Medical sciences
Full name of responsible person
Siamak Boustan
Position
Practitioner
Other areas of specialty/work
Street address
Imam Reza Hospital, Imam Reza square, Mashhad
City
Mashhad
Postal code
Phone
00989358937544
Fax
Email
professorsiamak@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Shima Sheybani

Position
Assistant Professor

Other areas of specialty/work

Street address
Anesthesia Department, Ghaem Hospital, Mashhad

City
Mashhad

Postal code

Phone
+98 51 1801 2612

Fax

Email
sheybanish@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Shima Sheybani

Position
Assistant Professor

Other areas of specialty/work

Street address
Anesthesia Department, Ghaem Hospital, Mashhad

City
Mashhad

Postal code

Phone
00

Fax

Email
sheybanish@mums.ac.ir

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