

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

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)

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. The major inclusion criterion to study: patients after undergoing elective off-pump coronary bypass. 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. Intervention group: Ringer lactate, 30 CC/kg at 24 hours after surgery. Control group: Isotonic saline 0.9%, 30 mL/kg at 24 hours after surgery. Primary outcome: Arterial blood gases, Before and at the first 24 hours after intervention, every 4 hour, By Blood test; Blood urea nitrogen, Before and after intervention, daily by venous blood samples from the arm; Blood creatinine level after intervention, daily by blood test, jaffe method

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041813159N3**

Registration date: **2014-06-15, 1393/03/25**

Registration timing: **registered_while_recruiting**

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

2014-05-25, 1393/03/04

Expected recruitment end date

2015-05-25, 1394/03/04

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 off-pump coronary bypass, hospitalized in the intensive care unit (ICU)

Public title

Diagnosis of acute kidney injury in patients undergoing off-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%, 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.

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**

2013-10-22, 1392/07/30

Ethics committee reference number

920805

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 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

Venous blood samples from the arm

3**Description**

Blood creatinine level

Timepoint

After intervention, daily

Method of measurement

Blood test, jaffe method

4**Description**

Sodium

Timepoint

Before 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

Daily after intervention

Method of measurement

Blood test

Intervention groups**1****Description**

Control group: Isotonic saline 0.9% containing 154 mEq chlorine ion, 30 ml/kg at 24 hours after surgery

Category

Diagnosis

2**Description**

Intervention group: Ringer lactate containing 109 mEq chlorine ion, 30 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

Elham Behnamfar

Street address

Imam Reza Hospital, Imam Reza Square, Mashhad

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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

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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

Elham Behnamfar

Position

Practitioner

Other areas of specialty/work**Street address**

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Assistant Professor

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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

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Shima Sheybani