

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

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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