

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Comparison of the effect of fluid therapy with Ringer and Ringer lactate solution on acid and base status and blood electrolytes in patients with coronary artery bypass graft surgery

Protocol summary

Study aim

The effect of using Ringer and Ringer lactate solutions on acid and base status and blood electrolytes in patients with coronary artery bypass graft surgery

Design

Design: 160 patients who are candidates for coronary artery bypass graft surgery are randomly divided into two groups. This clinical trial will have two parallel groups and one blind one.

Settings and conduct

This study will be performed in the operating room of Shahid Rajaei Cardiovascular Research Center.

Participants/Inclusion and exclusion criteria

Age 30 to 70 years - Weight 30 to 100 kg - No license for severe kidney or liver disease Absence of severe heart failure Exclusion criteria: -Cardiac arrest of the patient during surgery or on the first day in the intensive care unit, -Severe postoperative bleeding on the first day in the intensive care unit - The patient returns to the pump for any reason - Intra-aortic implantation of a balloon pump or ECMO - Transfer of the patient to the ICU with an open sternum -Need for high-dose inotropes

Intervention groups

After applying the principles of randomization and placing the patient in the intervention group and transferring the patient to the operating room, the necessary monitoring is connected and appropriate intravenous access is established. Is injected. Volume of maintenance fluid per hour according to the law 4ml / kg (initial 10 kg weight) 2ml / kg (second 10 kg weight) 1ml / kg (remaining weight), volume correction due to fasting before the patient's operation, blood volume compensation to be removed And inaccessibility of the vascular system, compensation of urinary out put excess in excess of 1 ml / kg/h during surgery and the first 24 hours of patient admission to the ICU with serum ringer lactate. Primary and secondary outcome variables are

measured at desired time points

Main outcome variables

level of blood lactate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161127031131N2**

Registration date: **2021-11-16, 1400/08/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-16, 1400/08/25**

Update count: **0**

Registration date

2021-11-16, 1400/08/25

Registrant information

Name

Rasoul Azarfarin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 2017

Email address

azarfarin@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of fluid therapy with Ringer and Ringer lactate solution on acid and base status and blood electrolytes in patients with coronary artery bypass graft surgery

Public title

A comparative study of fluid therapy with Ringer's and Ringer's lactate solution on acid and base status and blood electrolytes in patients with coronary artery bypass graft surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Age 30 to 70 years - 2.Weight 30 to 100 kg 3. No license for severe kidney or liver disease (creatinine more than 1.5 and liver enzymes more than 2 times normal) 4. Absence of severe heart failure (LVEF> 35%)

Exclusion criteria:

1. Cardiac arrest of the patient during surgery or on the first day in the intensive care unit, 2. Severe postoperative bleeding on the first day (more than 1000 ml) in the intensive care unit 3. The patient returns to the pump for any reason 4. Intra-aortic implantation of a balloon pump or ECMO for any reason 5.Transfer of the patient to the intensive care unit with an open sternum 6. Need for high-dose inotropes (epinephrine or norepinephrine greater than 0.2 micrograms per kilogram of body weight per minute)

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients are randomly assigned to two equal groups and for random assignment, permuted block randomization with quadruple blocks is used.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the patients are unaware of which group they are in, but the patient's caregivers (physician and nurse) and statistical analyst are aware. In this study, after obtaining the patient's consent, it is explained that in one of the two groups, Ringer serum or Ringer lactate serum is and at the time of serum administration in the

operating room, the patient is anesthetized and in the intensive care unit, anesthesia of patient continues and is unaware, and after waking up, the name of the serum is covered with the label that the nurse is under. .

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Rajaei Cardiovascular Research Center

Street address

Ayattollah Hashemi Highway, cross valiasr Ave.
Shahid Rajai Hospital

City

Tehran

Province

Tehran

Postal code

19956114331

Approval date

2021-09-21, 1400/06/30

Ethics committee reference number

IR.RHC.REC.1400.048

Health conditions studied**1****Description of health condition studied**

Use of Ringer lactate serum

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

1.level of lactate

Timepoint

1. When the patient enters the operating room 2. After induction of anesthesia 3. Time off from the pump 4.Upon entering the ICU 5.Until the hour after entering the ICU 6.12 hours after entering the ICU 7.18 hours after entering the ICU

Method of measurement

Arterial blood sample and blood gas analyzer

Secondary outcomes

1

Description

level of Sodium,

Timepoint

1. When the patient enters the operating room 2. After induction of anesthesia 3. Time off from the pump 4. Upon entering the ICU 5. Until the hour after entering the ICU 6. 12 hours after entering the ICU 7. 18 hours after entering the ICU

Method of measurement

Arterial blood sample and blood gas analyzer

2

Description

level of Potassium

Timepoint

1. When the patient enters the operating room 2. After induction of anesthesia 3. Time off from the pump 4. Upon entering the ICU 5. Until the hour after entering the ICU 6. 12 hours after entering the ICU 7. 18 hours after entering the ICU

Method of measurement

Arterial blood sample and blood gas analyzer

3

Description

Acidose

Timepoint

1. When the patient enters the operating room 2. After induction of anesthesia 3. Time off from the pump 4. Upon entering the ICU 5. Until the hour after entering the ICU 6. 12 hours after entering the ICU 7. 18 hours after entering the ICU

Method of measurement

Arterial blood sample and blood gas analyzer

4

Description

level of Bicarbonate

Timepoint

1. When the patient enters the operating room 2. After induction of anesthesia 3. Time off from the pump 4. Upon entering the ICU 5. Until the hour after entering the ICU 6. 12 hours after entering the ICU 7. 18 hours after entering the ICU

Method of measurement

Arterial blood sample and blood gas analyzer

Intervention groups

1

Description

Intervention group: After applying the principles of randomization and placing the patient in the intervention group and transferring the patient to the operating room, the necessary monitoring is connected and appropriate intravenous access is established. Is injected. Volume of maintenance fluid per hour according to the law 4ml / kg

(initial 10 kg weight) 2ml / kg (second 10 kg weight) 1ml / kg (remaining weight), volume correction due to fasting before the patient's operation, blood volume compensation to be removed And inaccessibility of the vascular system, compensation of urinary output excess in excess of 1 ml / kg/h during surgery and the first 24 hours of patient admission to the ICU with serum ringer lactate. Primary and secondary outcome variables are measured at desired time points..

Category

Treatment - Other

2

Description

Control group: In Control group the same volumes of Ringer's solution will be given and the lactate and electrolyte levels measured in same time intervals

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Cardiovascular Research Center

Full name of responsible person

Rasool Azarfarin

Street address

Highway Ayatollah hashemi Rafsanjani Exp, cross Valiasr St

City

Tehran

Province

Tehran

Postal code

19956114331

Phone

+98 21 2392

Email

razarfarin@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaei Cardiovascular Medical and Research Center

Full name of responsible person

Rasoul Azarfarin

Street address

Ayattollah Hashemi Highway, cross valiasr Ave. Shahid Rajai Hospital

City

Tehran

Province

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Postal code

19956114331

Phone

+98 21 2392 2017

Email

razarfarin@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rajaei Cardiovascular Medical and Research Center

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Rasool Azarfarin

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Email

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Rasoul Azarfarin

Position

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Email

razarfarin@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

After the end of the study

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Use in medical research

From where data/document is obtainable

razarfarin@yahoo.com

What processes are involved for a request to access data/document

Email

Comments