Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 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 areunaware 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 Potasium
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 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..
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
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Postal code
19956114331
Phone
+98 21 2392
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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
Tehran
Postal code
19956114331

Phone
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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
Street address
Ayattollah Hashemi Highway, cross valiasr Ave.
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Person responsible for updating data

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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