Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison effect of plasmalite A and lactate ringer in prime solution on acid and base status and electrolytes)Na.K.Ca)and lactate level and blood sugure in people with Diabet undergoing cardiac surgery with cardiopulmonary bypass

Protocol summary

Study aim
Determining the effect of plasmalyte A and Ringer's lactate in Prime solution on acid and base status and electrolytes (sodium, potassium, calcium) and lactate and blood sugar levels in people with diabetes undergoing heart surgery with cardiopulmonary bypass at Shahid Rajaei Cardiovascular Center

Design
RCT clinical trial (randomized controlled clinical trial) in two groups in parallel time and place and phase 3 on 60 patients and double-blind

Settings and conduct
A randomized and prospective controlled study is conducted on a total of 60 adult patients undergoing CPB for cardiac surgeries. Patients are divided into 2 groups: group I (Ringer Lactate) and group II (Plasmalyte-A) arterial blood sample before starting CPB, after starting CPB, then every hour until the end of the operation and then upon entering the ICU and After that, at 6, 12, 18, and 24 hours, for the purpose of analysis in the table of electrolytes and acid-base balance, lactate and blood sugar levels are considered.The participant and the clinical observer are unaware of the outcome

Participants/Inclusion and exclusion criteria
1- Age above 17 years 2- Elective surgeries 3- The first time of heart surgery (CABG) and valvular surgery 4- LVEF>30% 5- Being diabetic

Intervention groups
The intervention group is the people receiving plasmolyte and the control group is the people receiving Ringer's serum

Main outcome variables
Acid and base conditions Electrolytes (sodium, potassium, calcium) in the blood Blood lactate level blood sugar In people with diabetes

General information

Reason for update

Acronym
P&R

IRCT registration information
IRCT registration number: **IRCT20211031052921N1**
Registration date: **2022-12-19, 1401/09/28**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-19, 1401/09/28**
Update count: **0**

Registration date
2022-12-19, 1401/09/28

Registrant information

Name
Mahnaz Dastyarkohan

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3824 8499

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-11, 1401/09/20

Expected recruitment end date
2023-02-09, 1401/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison effect of plasmalite A and lactate ringer in prime solution on acid and base status and electrolytes)Na.K.Ca)and lactate level and blood sugure in people with Diabet undergoing cardiac surgery with cardiopulmonary bypass

Public title
Comparison effect of plasmalite A and lactate ringer in prime solution on acid and base status and electrolytes)Na.K.Ca)and lactate level and blood sugure in people with Diabet undergoing cardiac surgery with cardiopulmonary bypass at Rajaei Cardiovascular Center
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age above 17 years Elective surgeries The first time of heart surgery (CABG) and valvular surgery LVEF>30% Being diabetic
Exclusion criteria:
Creatinine higher than 1.5 Returning to the cardiopulmonary pump for any reason up to 24 hours after the operation Cardiopulmonary arrest during surgery and cardiopulmonary resuscitation Back to the operating room on the first day of surgery
Age
From **17 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **3**
3 Plasmolyte or Ringer's serum of 500 ml for each person
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization The study participants will be randomly allocated into two groups equally (allocation ratio: 1:1) by the permuted balance block technique (block of 4) and via a web-based application (https://www.sealedenvelope.com). Randomization concealment will be performed by using the sealed envelope method. The prepared envelopes will be given to the study PI for appropriate implication. All of the mentioned processes will be performed by one of our colleagues who doesn’t involve in implementing the intervention and outcome assessment.
Blinding (investigator's opinion)
Single blinded
Blinding description
The participant, who is a volunteer to participate in this study, is informed about the two types of serum received, but he does not know which type of serum will be primed, and the clinical supervisor of the outcome is similarly unaware of the type of serum received for prime, and is completely far from pre-determined judgment. He is overseeing the affairs
Placebo
Used
Assignment
Factorial
Other design features
مطالعه بر روی افراد دیابتی فقط انجام میشود

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Rajaei Hospital
Street address
Tehran Province, Tehran District 3, Valiasr Street, Hashemi Rafsanjani Hwy, No. At the beginning, 11151 19969 Niayesh Corner of Shahid Rajaei Cardiovascular Training, Research and Treatment Center
City
tehran
Province
Tehran
Postal code
1995614331
Approval date
2022-05-14, 1401/02/24
Ethics committee reference number
IR.RHC.REC.1401.014

Health conditions studied

1

Description of health condition studied
diabet
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Electrolytes (sodium, potassium, calcium) in the blood
Timepoint
Arterial blood sample before the start of CPB, after the start of CPB, then every hour until the end of the procedure and then upon entering the ICU and then at 6,

12, 18 and 24 hours for analysis in the electrolyte and balance table. Acid and base, lactate and blood sugar levels are considered.

Method of measurement

The validity of this tool is checked by the content validity method, which means that the supervisors and advisors will confirm its scientific validity by checking the form

2

Description

Blood lactate level

Timepoint

Arterial blood sample before the start of CPB, after the start of CPB, then every hour until the end of the procedure and then upon entering the ICU and then at 6, 12, 18 and 24 hours for analysis in the electrolyte and balance table. Acid and base, lactate and blood sugar le

Method of measurement

The validity of this tool is checked by the content validity method, which means that the supervisors and advisors will confirm its scientific validity by checking the form

3

Description

blood sugar

Timepoint

Arterial blood sample before the start of CPB, after the start of CPB, then every hour until the end of the procedure and then upon entering the ICU and then at 6, 12, 18 and 24 hours for analysis in the electrolyte and balance table. Acid and base, lactate and blood sugar levels

Method of measurement

The validity of this tool is checked by the content validity method, which means that the supervisors and advisors will confirm its scientific validity by checking the form

4

Description

Acid and base conditions

Timepoint

Arterial blood sample before the start of CPB, after the start of CPB, then every hour until the end of the procedure and then upon entering the ICU and then at 6, 12, 18 and 24 hours for analysis in the electrolyte and balance table. Acid and base, lactate and blood sugar levels

Method of measurement

The validity of this tool is checked by the content validity method, which means that the supervisors and advisors will confirm its scientific validity by checking the form

Secondary outcomes

1

Description

Blood hemoglobin level

Timepoint

Arterial blood samples are evaluated before the start of CPB, after the start of CPB, then every hour until the end of the procedure, and then upon entering the ICU, and after that at 6, 12, 18, and 24 hours. The blood sample is taken using a Technomedia blood gas analyzer

Method of measurement

Hemoglobin level is also checked using an arterial blood sample which is a blood cell count check

Intervention groups

1

Description

The intervention group includes people receiving plasmolyte serum, which is prepared by Saman Mashhad company and is used for the prime of the cardiopulmonary bypass device of the patients under study, and in terms of osmolality, it is the most similar serum to the patient's blood. And for each patient, there are about three serums. One liter of plasmolite is used

Category

N/A

2

Description

Control group: The recipients of Ringer's lactate serum are considered to be recipients. About three one-liter Ringer's lactate serums are used for the prime of the cardiopulmonary bypass machine for volunteers. Its osmolarity is 280 and it is available in large numbers in Iran in recent years.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaei hospital

Full name of responsible person

Rasool Azarfarin

Street address

Tehran Province, Tehran District 3, Valiasr Street, Hashemi Rafsanjani Hwy, No. At the beginning, 11151 19969

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Rajaei Heart and Vascular Hospital Research Center

Full name of responsible person
Rasool Azarfarin

Street address
Tehran Province, Tehran District 3, Valiasr Street, Hashemi Rafsanjani Hwy, No. At the beginning, 11151 19969

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Rajaei Heart and Vascular Hospital 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
Shahid Rajaee Heart and Vascular Hospital's Medical Research Training Center

Full name of responsible person
rasoolazarfarin

Position
professor

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
the university of iran.rajaei hospital

Full name of responsible person
Dr Rasool Azarfarin

Position
Anesthsiologist Proffesor

Latest degree
Subspecialist

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Dr Rasool Azarfarin

Position
Anesthesiologist Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The informed consent form is available to all participants in the study, and all of them can be informed about the type of substance they have received. The clinical report is attached as a document after the completion of the work and the result

When the data will become available and for how long

All information will be available in the second half of 1402

To whom data/document is available

People participating in the study if interested Clinical supervisors The researcher and all the people who somehow contributed to the progress of the study

Under which criteria data/document could be used

In the form of a thesis and a written file in the library of Rajaei Hospital

From where data/document is obtainable

To the curator of Rajaei hospital library

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

This possibility of access is provided by visiting the library of Rajaei Hospital in person

Comments

There is no additional explanation