

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 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 sugar in people with Diabetes 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)

##### Phone

+98 71 3824 8499

##### Email address

dastyarkohanmahnaz@gmail.com

##### 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 sugar 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 sugar 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 Technomedica 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

##### **City**

Tehran

##### **Province**

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##### **Postal code**

1995614331

##### **Phone**

+98 921 248 3155

##### **Email**

dastyarkohanmahnaz@gmail.com

## **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

**City**

Tehran

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**Phone**

+98 21 2204 2026

**Email**

dastyarkohanmahnaz@gmail.com

**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 Rajaei 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

**Street address**

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

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**Postal code**

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**Phone**

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**Email**

dastyarkohanmahnaz@gmail.com

### 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**

Anesthesiologist Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Nursery

**Street address**

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dastyarkohanmahnaz@gmail.com

### Person responsible for updating data

**Contact****Name of organization / entity**

Shahid Rajaei educational research and treatment center

**Full name of responsible person**

Dr Rasool Azarfarin

**Position**

Anesthesiologist Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

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

**City**

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**Postal code**

1995614331

**Phone**

23921-021

**Email**

razarfarin@gmail.com

## 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