

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The Effect of Calcium Gluconate Injection on Hemodynamic Variables During Cardiopulmonary Bypass and Clinical Outcome in infants Under Open Heart Surgery

#### Protocol summary

Correction of hemodynamic variables and improvement of cardiac function in the intensive care unit

#### Study aim

Determining and comparing the mean (Systolic and diastolic blood pressure, Arterial blood pressure, Consumption of inotropes, Heart rate, Arterial blood gas levels, Cardiac output fraction) And the frequency of postoperative blood transfusions in the intervention and control groups

#### Design

This study is a randomized controlled clinical trial with single-blind (patient unaware of the intervention). Patients were divided into 2 groups of 30 by random randomization (Block randomization) with size 6.

#### Settings and conduct

This intervention will be performed in Shahid Rajaei Cardiovascular Educational, Research and Treatment Center in 1400 in children. The study population included all infants who were candidates for open heart surgery weighing up to 10 kg.

#### Participants/Inclusion and exclusion criteria

- 1) Parents' consent to participate in the research project
- 2) Sick infants up to 10 kg candidate for open heart surgery
- 3) Normal and lower ionized calcium during cardiopulmonary bypass
- 4) Absence of any metabolic and systemic diseases that affect the level of calcium gluconate
- 5) Do not take digoxin before surgery by the patient
- 6) The patient does not have hypophosphatemia
- 7) Patients who do not undergo reoperation or emergency surgery

#### Intervention groups

The study population included all sick children who were candidates for open heart surgery weighing up to 10 kg. In the first group, intravenous injection of calcium gluconate at a rate of 100 mg / kg at a rate of 25 mg / kg per minute up to a maximum of 1 gram, 20 minutes after opening the aortic clamp and the second group will be evaluated as a control.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210316050726N1**

Registration date: **2021-09-06, 1400/06/15**

Registration timing: **retrospective**

Last update: **2021-09-06, 1400/06/15**

Update count: **0**

##### Registration date

2021-09-06, 1400/06/15

##### Registrant information

##### Name

Saeed Rajabzade zaree

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2610 2319

##### Email address

saeed.rajabzade@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-05, 1400/05/14

##### Expected recruitment end date

2021-09-05, 1400/06/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
The Effect of Calcium Gluconate Injection on Hemodynamic Variables During Cardiopulmonary Bypass and Clinical Outcome in infants Under Open Heart Surgery

**Public title**  
The Effect of Calcium Gluconate Injection on Hemodynamic Variables

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

- 1) Parents' consent to participate in the research project
- 2) infants up to 10 kg candidate for open heart surgery
- 3) Normal and lower ionized calcium during cardiopulmonary bypass (1.2 to 1.38 mmol / lit)
- 4) Absence of any metabolic and systemic diseases that affect the level of calcium gluconate
- 5) Do not take digoxin before surgery by the patient
- 6) The patient does not have hypophosphatemia
- 7) Patients who do not undergo reoperation or emergency surgery

**Exclusion criteria:**

**Age**  
No age limit

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Infants of candidates for open heart surgery were divided into 6 groups (10 blocks of 6) permuted block randomization using create a randomization list software into two groups of 30 people.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
This study is a randomized controlled clinical trial with a single blind (patient not knowing about the intervention) and after obtaining informed consent from the patient's parents and observing the inclusion cases, the patient is anesthetized due to surgery and intervention.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Ethics Committee of Shahid Rajaei Cardiovascular University

**Street address**

Shaheed Rajaie Cardiovascular Medical and Research Center Valiasr Ave Niayesh Intersection Tehran Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1995614331

**Approval date**

2021-08-03, 1400/05/12

**Ethics committee reference number**

IR.RHC.REC.1400.042

## Health conditions studied

### 1

#### Description of health condition studied

Cyanotic congenital heart disease

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

#### Description

mid arterial pressure

#### Timepoint

Researcher at intervals before induction of anesthesia, after induction of anesthesia, during cardiopulmonary bypass, during warm-up, after opening of aortic clamp, after calcium injection, after termination of cardiopulmonary bypass, upon entering the ICU 2, 4, 6 and 8 hours after entering the ICU will be extracted and collected through the records and test sheets of the studied patients.

#### Method of measurement

Based on the patient's cardiovascular monitor

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: children are candidates for open heart surgery weighing up to 10 kg. In this group, intravenous injection of calcium gluconate at a rate of 100 mg / kg at a rate of 25 mg / kg per minute up to a

maximum of 1 g was performed 20 minutes after opening the aortic clamp.

**Category**

Treatment - Drugs

**2****Description**

Control group: children are candidates for open heart surgery weighing up to 10 kg

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Rajaei Cardiovascular Hospital

**Full name of responsible person**

saeed rajabzade zaree

**Street address**

Shahid Rajaei Cardiovascular Training, Research and Treatment Center, Vali Asr St. Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1995614331

**Phone**

+98 21 23921

**Email**

saeed.rajabzade@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

saeed rajabzade zaree

**Street address**

Shaheed Rajaie Cardiovascular Medical and Research Center Valiasr Ave Niayesh Intersection Tehran Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1995614331

**Phone**

+98 21 23921

**Email**

saeed.rajabzade@yahoo.com

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

Yes

**Title of funding source**

Iran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

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

Persons

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

Iran University of Medical Sciences

**Full name of responsible person**

majid maleki

**Position**

specialist

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Cardiology

**Street address**

Shaheed Rajaie Cardiovascular Medical and Research Center Valiasr Ave Niayesh Intersection Tehran Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1995614331

**Phone**

+98 21 23921

**Email**

saeed.rajabzade@yahoo.com

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

Iran University of Medical Sciences

**Full name of responsible person**

saeed rajabzade zaree

**Position**

Masters student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Nursery

**Street address**

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**Email**  
saeed.rajabzade@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
saeed rajabzade zaree  
**Position**  
Masters student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Shaheed Rajaie Cardiovascular Medical and Research  
Center Valiasr Ave Niayesh Intersection Tehran Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no more information

### 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

No - There is not a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be 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