Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effect of Calcium Gluconate drip treatment in pediatrics with normal calcium level after cardiac surgery

Protocol summary

Study aim

Due to ongoing controversy regarding calcium gluconate use in cardiac surgery patients, further evaluation of its effects on postoperative outcomes may have important implications for patient management and clinical outcomes.

Design

Children will be randomly assigned to hypocalcemia and normal calcium groups receiving different doses of intravenous calcium gluconate to reach target serum calcium levels. The study is double-blind, and the drug is prepared similar to normal saline. Data will be analyzed using SPSS version 22.

Settings and conduct

This randomized clinical trial will be conducted at Shahid Modarres Hospital on pediatric patients after cardiac surgery. Patients will be assigned to hypocalcemia and normal calcium groups and will receive calcium gluconate. The study is double-blind, and the drug is prepared similarly to normal saline for blinding.

Participants/Inclusion and exclusion criteria

Inclusion Age ≤18 years Hospitalization for cardiac surgery Documented serum calcium level Exclusion Underlying metabolic or endocrine disorders Severe non-cardiac illness Refusal of patient/parent/legal guardian consent Serious adverse events during the study History of hypersensitivity to calcium gluconate

Intervention groups

Hospitalized pediatric patients after cardiac surgery will be enrolled following informed consent. Patients with hypocalcemia will receive standard calcium therapy, while those with normal calcium levels will receive continuous calcium gluconate infusion until a predefined upper target level. Clinical outcomes will be compared between the two groups.

Main outcome variables

ICU and hospital length of stay; mortality/overall outcome; serum calcium levels; mechanical ventilation; inotropic support; hemodynamic changes ; major complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260615069812N1**
Registration date: **2026-10-05, 1405/07/13**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-05, 1405/07/13**
Update count: **0**

Registration date

2026-10-05, 1405/07/13

Registrant information

Name
maryam zeinali
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2208 3101
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maryamzeinali@sbmu.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-20, 1405/03/30

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of Calcium Gluconate drip treatment in pediatrics with normal calcium level after cardiac surgery

Public title
Calcium Gluconate drip treatment in pediatrics with normal calcium level after cardiac surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age ≤ 18 years Hospitalization for cardiac surgery-related disease Availability of documented serum calcium level measurements

Exclusion criteria:
Presence of underlying metabolic or endocrine disorders Severe non-cardiac medical illness Refusal of participation by the patient or parent/legal guardian Development of severe adverse events during the study History of hypersensitivity to calcium gluconate

Age
To **19 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Group 1 (Hypocalcemic Group): Patients with hypocalcemia will receive intravenous calcium gluconate infusion at a dose of 1 mg/kg/hour. The infusion will be continued until the serum calcium level reaches the normal range, defined as at least 8.5 mg/dL. Group 2 (Normocalcemic Group): Children with normal serum calcium levels will receive intravenous calcium gluconate infusion at a dose of 0.5 mg/kg/hour. The infusion will be continued until the serum calcium level reaches the upper normal limit of 10.5 mg/dL, after which the infusion will be discontinued.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be conducted using a double-blind design, whereby neither the investigators nor the parents/legal guardians will be aware of the treatment allocation. To maintain blinding, calcium gluconate infusions and placebo (normal saline) infusions will be prepared and administered in an identical manner.

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Shahid Modarres Hospital, Yadegar-e-Emam Highway, Saadat Abad intersection, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1998734421

Approval date
2024-10-27, 1403/08/06

Ethics committee reference number
IR.SBMU.RETECH.REC.1403.438

Health conditions studied

1

Description of health condition studied
Children undergoing cardiac surgery

ICD-10 code
Q20

ICD-10 code description
Congenital malformations of cardiac chambers and connections

Primary outcomes

1

Description
Calcium level, duration of ICU and hospital stay, duration of intubation, and the degree of inotrope requirement

Timepoint
Serum calcium levels in children are measured at specific time points (before the start of treatment, during the course of treatment, and after completion of treatment).

Method of measurement
Medical record.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group 1 consists of patients with hypocalcemia who receive intravenous calcium gluconate treatment. The dose of calcium gluconate in this group is 1 mg/kg/hour administered as an intravenous drip until the serum calcium level reaches at least the normal range (≥ 8.5 mg/dL). In Group 2, children with normal serum calcium levels receive a calcium gluconate infusion at a dose of 0.5 mg/kg/hour. The infusion is continued until the serum calcium level reaches a higher target (> 10.5 mg/dL), after which the infusion is discontinued.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Modarres Hospital

Full name of responsible person
Kourosh Vahidshahi

Street address
Yadegar-e-Emam Highway, Saadatabad Junction, Shahid Modares Hospital, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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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 Beheshti University of Medical Sciences

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 Beheshti University of Medical Sciences

Full name of responsible person
maryam zeinali

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
pediatric cardiology

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Latest degree
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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

The data and study-related documents will be shared only after all personal identifiers and confidential information have been removed. De-identified data may be made available to qualified researchers upon reasonable request and with approval from the principal investigator, solely for scientific and research purposes. Data sharing will be conducted through secure electronic transfer or by depositing the data in an appropriate research data repository, where applicable. The study protocol, data collection instruments, and other relevant study documents may also be shared upon request, provided that confidentiality and ethical requirements are fully maintained. All data sharing will be carried out in accordance with applicable research ethics guidelines and data protection regulations.

When the data will become available and for how long

Data will be available upon completion of data collection

To whom data/document is available

Principal Investigator, study team members, and qualified researchers upon reasonable request and approval

Under which criteria data/document could be used

For scientific and research purposes only, subject to confidentiality requirements and approval by the Principal Investigator.

From where data/document is obtainable

The Principal Investigator of the study (email)

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

Data/document access requests will be reviewed by the Principal Investigator. Access will be granted after approval of the request and confirmation of compliance with confidentiality and research ethics requirements.

Comments