Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Comparing the effects of vitamin D and placebo on the treatment course of neonates, infants, and children with congenital heart disease following corrective heart surgery

Protocol summary

Study aim
To compare the effects of vitamin D and placebo on the treatment course of neonates, infants, and children with congenital heart disease following corrective heart surgery

Design
In this study, 46 eligible pediatric patients with congenital heart disease who are candidates for corrective heart surgery referring to the heart ward of Razi Hospital affiliated with Birjand University of Medical Sciences will be selected. Participants will be assigned non-randomly to intervention and control groups, and each participant will be assigned a code.

Settings and conduct
This single-blinded study will be conducted in the cardiac surgery department of Razi Hospital affiliated with Birjand University of Medical Sciences. Patients in the intervention group will receive oral vitamin D before surgery, and patients in the control group will receive a placebo. The patient's symptoms will be evaluated by the researcher 24 and 48 hours postoperatively. Based on the patient's condition, inotropic drugs will be prescribed.

Participants/Inclusion and exclusion criteria
Major inclusion criteria: Suffering from congenital heart disease; risk adjustment for congenital heart surgery score below 5; age below or equal to 18 years; serum vitamin D level below or equal to 150 nanograms per milliliter. Major exclusion criteria: Vitamin D contraindications and being treated with steroidal drugs.

Intervention groups
Intervention group: Before surgery, 300,000 units of vitamin D will be given orally in the form of six 50,000 unit pearls soaked in water. Control group: The patients will receive placebo in the form of an oral solution, which is similar in appearance and volume to the vitamin D solution and appropriate for their age group.

Main outcome variables
Inotrope Score; Vasoactive-Inotrope Score

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170316033099N6**
Registration date: **2019-02-09, 1397/11/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-09, 1397/11/20**
Update count: **0**

Registration date
2019-02-09, 1397/11/20

Registrant information
Name
Mohammad Bagher Roozgar
Name of organization / entity
Birjand University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-12-22, 1397/10/01
Expected recruitment end date
2019-06-21, 1398/03/31
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effects of vitamin D and placebo on the treatment course of neonates, infants, and children with congenital heart disease following corrective heart surgery

Public title
Effect of vitamin D on the improvement of infants and children with congenital heart disease
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering from congenital heart disease Risk adjustment for congenital heart surgery score below 5 Age below or equal to 18 years Serum vitamin D level below or equal to 150 nanograms per milliliter Consent from parent or legal guardian to participate in the study The patient being candidate for open heart surgery
Exclusion criteria:
Being treated with steroidal drugs Vitamin D contraindications Application of cardio-respiratory support device Contraindications for oral medication Active cardiopulmonary resuscitation
Age
From **1 day** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
The purpose of the study is explained to the participants. However, they are not told into which group of the study they are assigned.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Birjand University of Medical Sciences
Street address
Ghaffari Ave.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Approval date
2018-03-05, 1396/12/14
Ethics committee reference number
IR.BUMS.REC.1397.301

Health conditions studied

1

Description of health condition studied
congenital heart disease
ICD-10 code
Q24.9
ICD-10 code description
Congenital malformation of heart, unspecified

Primary outcomes

1

Description
Vasoactive-Inotrope Score
Timepoint
24 and 48 hours postoperatively
Method of measurement
Vasoactive-Inotrope Score calculation formula

2

Description
Vasoactive-Inotrope Score
Timepoint
24 and 48 hours postoperatively
Method of measurement
Inotrope Score calculation formula

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (Vitamin D): Before surgery, 300,000 units of vitamin D will be given orally in the form of six 50,000 unit pearls soaked in water.

Category
Treatment - Drugs

2

Description
Control group (placebo): The patients will receive placebo in the form of an oral solution, which is similar in appearance and volume to the vitamin D solution and appropriate for their age group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Heart ward of Razi Hospital
Full name of responsible person
Dr. Emad Askari Jafarabadi
Street address
Ghaffari Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Dr Tooba Kazemi
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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
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Dr. Emad Askari Jafarabadi
Position
Pediatric diseases assistant
Latest degree
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Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mohammad Bagher Roozgar

Position

Translator

Latest degree

Master

Other areas of specialty/work

Others

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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

Not applicable

Title and more details about the data/document

Deidentified Individual Participant Data Set

When the data will become available and for how long

When the paper extracted from the project is published and for six months

To whom data/document is available

readers of the paper

Under which criteria data/document could be used

Research purposes

From where data/document is obtainable

personal correspondence with the corresponding author

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

email

Comments