

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

Country

Iran (Islamic Republic of)

Phone

+98 56 3239 5680

Email address

roozgar@bums.ac.ir

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 centers1**Recruitment center****Name of recruitment center**

Heart ward of Razi Hospital

Full name of responsible person

Dr. Emad Askari Jafarabadi

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Ghaffari Ave.

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Sponsors / Funding sources1**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

Medical doctor

Other areas of specialty/work

Pediatrics

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Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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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