

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Study of vitamin D level correction on mortality rate and postoperative complications in children after VSD repair surgery in Shahid Chamran Hospital in Isfahan

Protocol summary

Study aim

The effect of vitamin D level correction on mortality and morbidity after pediatric intraventricular wall defect repair in Shahid Chamran Hospital, Isfahan

Design

Randomized controlled clinical trial

Settings and conduct

The data are collected from observation and recorded in the checklist. 32 children with VSD are eligible for VSD repair surgery. A blood sample is prepared prior to surgical excision and vitamin D levels are checked. Vitamin D is lower than normal for calcium and phosphorus (ca / p), albumin and PTH tests from the same blood sample and a blood sample from children referred to the physician's office according to the 32-child intervention group. The test is administered and prescribed for one month or more of vitamin D supplementation of IU400 daily for less than one year and IU600 daily for more than one year. Give one day daily, then check for a sample of vitamin D before surgery. Twenty-four hours after surgery, a re-sample of the control and test groups was taken to measure vitamin D levels.

Participants/Inclusion and exclusion criteria

1- Age range from one month to six years 2. The patient should undergo open heart surgery using a cardiopulmonary pump. 3. Parents of children have informed consent to study. Non-arrival conditions 1- Patient's parents' unwillingness to participate in the study 2. Complex heart disease 3. Emergency surgery 4. Multi-stage surgery 5. Died during the intervention 6. Children with abnormal blood albumin or PTH level 7- Children with a positive family history of kidney stones who are inherently higher in vitamin D

Intervention groups

Children referred to a physician had inadequate vitamin D levels and were supplemented with vitamin D

supplementation of 400 units for less than one year and 600 units for one year or more for one month or more.

Main outcome variables

Inotrop Score , ICU and hospital stay, mortality, Intubation Time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200123046231N1**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **retrospective**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

Registration date

2020-02-01, 1398/11/12

Registrant information

Name

Seyed Mansour Shefaat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

mshefaat@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-01-19, 1398/10/29

Actual recruitment start date

2019-05-21, 1398/02/31

Actual recruitment end date

2020-01-19, 1398/10/29

Trial completion date

2020-01-20, 1398/10/30

Scientific title

Study of vitamin D level correction on mortality rate and postoperative complications in children after VSD repair surgery in Shahid Chamran Hospital in Isfahan

Public title

Study of vitamin D level modification on mortality rate and postoperative complications in children after VSD repair surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient undergo open heart surgery using a heart pump and pulmonary pump Age range from one month to six years Parents of children have informed consent to study

Exclusion criteria:

Patient's parents' unwillingness to participate in the study Complex heart disease Emergency surgery Multi-stage surgery Died during the intervention Children with abnormal blood albumin or PTH levels will be excluded. Children who take vitamin D concomitantly with corticosteroid drugs such as prednisolone, anticonvulsants such as phenobarbital and phenytoin, and tuberculosis drugs such as rifampin and isoniazid with various mechanisms including decreased calcium absorption, decreased vitamin D absorption, increased metabolism of vitamin D and vitamin D Reduces the effect of vitamin D. Therefore, they need to increase their vitamin D intake Children with a positive family history of kidney stones that are inherently higher in vitamin D will be excluded from the study Children who use anesthetic drugs that interfere with vitamin D levels during cardiopulmonary bypass will be excluded

AgeFrom **1 month** old to **6 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **64**Actual sample size reached: **64****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Nothing

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of isfahan university of medical sciences

Street address

Hezar jarib in Blvd.

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Postal code

8159636937

Approval date

2019-10-20, 1398/07/28

Ethics committee reference number

IR.MUI.MED.REC.1398.370

Health conditions studied**1****Description of health condition studied**

Ventricular septal Defect

ICD-10 code

Q21.0

ICD-10 code description

Ventricular septal defect

Primary outcomes**1****Description**

Serum vitamin D levels in children

Timepoint

Baseline, before surgical incision, 24 hours after surgery

Method of measurement

HPLC method

Secondary outcomes**1****Description**

Mortality rate

Timepoint

After surgery

Method of measurement

Follow-up until discharge

2

Description

inotrop Score

Timepoint

when detached from Cardiopulmonary Machine, Highest in the first 24 ICU admissions

Method of measurement

Inotrope Score (IS) = Dopamine dose (mcg/kg/min) + Dobutamine dose (mcg/kg/min) + 100 x Epinephrine dose (mcg/kg/min)

3

Description

Intubation Time

Timepoint

After surgery

Method of measurement

The patient's intubation hours after surgery

4

Description

Length of stay in intensive care unit

Timepoint

After surgery

Method of measurement

Days in the intensive care unit after surgery

5

Description

Duration of hospitalization

Timepoint

From patient admission to discharge

Method of measurement

Number of hospital days

Intervention groups

1

Description

Intervention group: Children referred to physicians who had inadequate vitamin D levels and underwent non-emergency surgery for ventricular septal defect repair were given 400 international units daily for children under one year and 600 international units for children over one year old. They were supplemented with vitamin D drops for a month or more

Category

Other

2

Description

Control group: Children on the list of non-emergency surgery for repair of the ventricular septal defect who did not have access to vitamin D level control

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid chamran Heart Center Isfahan

Full name of responsible person

Seyed Mansoor Shefaat

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Salman Farsi Blvd.

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Web page address

<https://chamran.mui.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Shaghayegh Haghjuy Javanmard

Street address

Hezar Jarib Street, Isfahan University of Medical Sciences, Staff Building No. 5 - Vice chancellor for research and Technology

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sh_haghjoo@med.mui.ac.ir

Web page address

<https://research.mui.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Seyed Mansour Shafaat

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

All potential data is shared after unidentifiable people

When the data will become available and for how long

Start access period 4 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

All investigations should be conducted with the coordination of the researcher

From where data/document is obtainable

Correspondence Email to mshefaat2005@gmail.com

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

The data will be sent as a PDF file after obtaining written permission from the Vice President of Research and Technology of the University of Medical Sciences at least one month after the researchers request.

Comments