Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 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 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

+98 31 3230 6139

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
Age
From **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.
City
Isfahan
Province
Isfehan
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
Street address
Salman Farsi Blvd.
City
Isfahan
Province
Isfehan
Postal code
8159636944
Phone
+98 31 3260 0961
Email
dean@med.mui.ac.ir
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
City
Isfahan
Province
Isfehan
Postal code
73461-81746
Phone
+98 31 3668 8138
Email
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
Street address
Talar Ave, Pardis alley, No. 18
City
Isfahan
Province
Isfehan
Postal code
8199917999
Phone
+98 31 3230 6139
Email
mshefaat2005@gmail.com

Person responsible for scientific 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
Street address
Talar Ave, Pardis alley, No. 18
City
Isfahan
Province
Isfehan
Postal code
8199917999
Phone
+98 31 3230 6139
Email
mshefaat2005@gmail.com

Person responsible for updating data

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
Street address
Talar Ave, Pardis alley, No. 18
City
Isfahan
Province
Isfehan
Postal code
8199917999
Phone
+98 31 3230 6139
Email
mshefaat2005@gmail.com

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