

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Influence of Dexmedetomidine on Pulmonary Hypertensive Crisis and Arrhythmias and Extubation Time in Cardiac Surgery Patients with Left to Right Shunt and Severe PH

Protocol summary

Summary

Objective: to evaluate the effect of dexmedetomidine on pulmonary hypertension and irregular heartbeat and extubation time in patients after heart surgery with left to right shunt and severe pulmonary hypertension. Study design: prospective randomized study. Inclusion criteria: children under one year old who are undergoing elective cardiac surgery for Ventricular septal defect, severe pulmonary hypertension and left to right shunt. Exclusion criteria: severe hepatic failure; renal failure ($Cr \geq 1 / 5$); heart block; primary hypotension; bradycardia. Method: 66 patients under one-year-old with the Ventricular septal defect or left to right shunt and severe pulmonary hypertension randomly divided into 2 groups. In dexmedetomidine group from the beginning of cardiopulmonary bypass in addition to the common drugs like Milrinone and Sildenafil, intravenous infusion of dexmedetomidine will be administered ($0.5 \mu\text{g/kg/hr.}$) and continued for 24 hours. While, Dexmedetomidine was not used in control group. Pulmonary hypertension, arrhythmia and extubation time are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081619470N40**
Registration date: **2017-04-19, 1396/01/30**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-04-19, 1396/01/30

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Influence of Dexmedetomidine on Pulmonary Hypertensive Crisis and Arrhythmias and Extubation Time in Cardiac Surgery Patients with Left to Right Shunt and Severe PH

Public title

Influence of Dexmedetomidine on Pulmonary Hypertensive Crisis and Arrhythmias and Extubation Time in Cardiac Surgery Patients with Left to Right Shunt and Severe PH

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All children under one year old undergoing elective surgery and have severe pulmonary hypertension and left to right shunt. Exclusion criteria: severe hepatic failure, renal failure (Cr ≥ 1 / 5); heart block; primary hypotension, bradycardia.

Age

To 1 year old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 66

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Postal code

Approval date

2014-08-20, 1393/05/29

Ethics committee reference number

IR.SUMS.REC.1394.128

Health conditions studied

1

Description of health condition studied

Congenital heart disease

ICD-10 code

Q24

ICD-10 code description

Other congenital malformations of heart

Primary outcomes

1

Description

arrhythmias

Timepoint

At 0,6,12, 24, 48, 72hours during surgery and after surgery in the ICU.

Method of measurement

EKG monitoring

Secondary outcomes

1

Description

pulmonary artery pressure

Timepoint

After surgery and after pulmonary artery catheter insertion in the intensive care unit.

Method of measurement

pulmonary artery catheter

2

Description

Patient's extubation time

Timepoint

After transferring patient to the intensive care unit.

Method of measurement

observation

Intervention groups

1

Description

In dexmedetomidine group apart from common drugs used to manage anesthesia and pulmonary hypertension in patients with severe pulmonary hypertension like Milrinone and Sildenafil, dexmedetomidine began to be used in intravenous infusion with the dose of 0.5 $\mu\text{g/kg/hr}$. from the beginning of cardiopulmonary bypass and continued for 24 hours.

Category

Treatment - Drugs

2

Description

In the control group apart from common drugs used to manage anesthesia and pulmonary hypertension in patients with severe pulmonary hypertension like Milrinone and Sildenafil, Dexmedetomidine was not used in intravenous infusion.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahi Faghihi Hospital

Full name of responsible person

Bahdor Azizi

Street address

Shahid Faghihi Hospital, Zand Street

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

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Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Bahador Azizi

Position

cardiovascular perfusionist

Other areas of specialty/work

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Other areas of specialty/work

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Full name of responsible person

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Position

MS in english teaching ,BS in anesthesia/English Consultant

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty