

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of preoperative dexmedetomidine use and acute kidney injury in pediatric patients with congenital heart disease undergoing open cardiac surgery

Protocol summary

Study aim

Objective: The effect of perioperative dexmedetomidine use and acute kidney injury in pediatric patients with congenital heart disease undergoing open cardiac surgery .

Design

Study design: Double blind randomized clinical trial.

Settings and conduct

Intervention: After inserting the central venous catheter, the blood sample is sent to the laboratory for evaluation of serum creatinine. In the group (D), 0.4 µg / kg / hr. of dexmedetomidine infusion were administered after anesthesia induction until the end of the operation. In the control group (C) the same volume of normal saline will be administered, which continues until the end of the operation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 70 children aged 6 months to 8 years with congenital heart disease who are candidates for open heart surgery. Exclusion Criteria: Emergency surgery, re-operation (re-do), heart failure, preoperative renal failure (Serum Cr> 2 mg / dl), liver failure, use of inotropic or vasopressor prior to surgery, need Deep hypothermic circulatory arrest during surgery

Intervention groups

Intervention: After inserting the central venous catheter, the blood sample is sent to the laboratory for evaluation of serum creatinine. In the group (D), 0.4 µg / kg / hr. of dexmedetomidine infusion were administered after anesthesia induction until the end of the operation. In the control group (C) the same volume of normal saline will be administered, which continues until the end of the operation.

Main outcome variables

The serum level of creatinine, GFR: Glomerular filtration rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130816014372N10**

Registration date: **2019-04-26, 1398/02/06**

Registration timing: **prospective**

Last update: **2019-04-26, 1398/02/06**

Update count: **0**

Registration date

2019-04-26, 1398/02/06

Registrant information

Name

Simin Azemati

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-25, 1398/03/04

Expected recruitment end date

2019-07-26, 1398/05/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street
Scientific title	City
The effect of preoperative dexmedetomidine use and acute kidney injury in pediatric patients with congenital heart disease undergoing open cardiac surgery	Shiraz
	Province
	Fars
Public title	Postal code
The effect of preoperative dexmedetomidine use and acute kidney injury in pediatric patients with congenital heart disease undergoing open cardiac surgery	7134844119
Purpose	Approval date
Prevention	2017-06-23, 1396/04/02
Inclusion/Exclusion criteria	Ethics committee reference number
Inclusion criteria:	IR.SUMS.MED.REC.1396.41
children aged 6 months to 8 years congenital heart disease Children who are candidates for open heart surgery	
Exclusion criteria:	Health conditions studied
Emergency operation Re-do Operation heart failure preoperative renal failure (Serum Cr> 2 mg / dl Liver failure Use of inotropic or vasopressor prior to surgery Need Deep hypothermic circulatory arrest during surgery	1
Age	Description of health condition studied
From 6 months old to 8 years old	Congenital heart disease
Gender	ICD-10 code
Both	Q24.9
	ICD-10 code description
Phase	Congenital malformation of heart, unspecified
2-3	
Groups that have been masked	Primary outcomes
No information	1
Sample size	Description
Target sample size: 70	Inotrope Score
Randomization (investigator's opinion)	Timepoint
Not randomized	Intra-operatively and 3 days after operation.
Randomization description	Method of measurement
Blinding (investigator's opinion)	Inotrope Score (IS)Vasoactive – inotropic score (VIS)
Double blinded	
Blinding description	Secondary outcomes
Dexmedetomidine and normal saline are prepared by an anesthesia nurse who is not involved in the study and will provide to the researcher with a randomized table.	empty
Placebo	Intervention groups
Used	1
Assignment	Description
Single	Intervention group: In the group (D), 0.4 µg / kg / hr. of dexmedetomidine infusion were administered after anesthesia induction until the end of the operation.
Other design features	Category
	Prevention
Secondary Ids	2
empty	Description
Ethics committees	Control group: In the control group (C) same volume of normal saline will be administered, which continues until the end of the operation.
1	Category
Ethics committee	Prevention
Name of ethics committee	
Ethics committee of Shiraz University of Medical Sciences	Recruitment centers
Street address	
Vice Chancellor of research, Shiraz University of	

1

Recruitment center

Name of recruitment center

khalili Hospital

Full name of responsible person

Sheema Eskandari

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khalili Hospital, Namazi Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

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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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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Sheema Eskandari

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

Subspecialist

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available