

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)

Phone

+98 71 1647 4270

Email address

azemati@sums.ac.ir

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

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

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

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
children aged 6 months to 8 years congenital heart disease Children who are candidates for open heart surgery
Exclusion criteria:
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

Age
From **6 months** old to **8 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
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.

Placebo
Used

Assignment
Single

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

Province

Fars

Postal code

7134844119

Approval date

2017-06-23, 1396/04/02

Ethics committee reference number

IR.SUMS.MED.REC.1396.41

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

Inotrope Score

Timepoint

Intra-operatively and 3 days after operation.

Method of measurement

Inotrope Score (IS)Vasoactive – inotropic score (VIS)

Secondary outcomes

empty

Intervention groups

1

Description

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.

Category

Prevention

2

Description

Control group: In the control group (C) same volume of normal saline will be administered, which continues until the end of the operation.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

khalili Hospital

Full name of responsible person

Sheema Eskandari

Street address

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

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Simin Azemati

Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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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