

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Effects of S-medtomidine infusion on pro- and anti-inflammatory cytokines in pediatric open heart surgery

Protocol summary

Summary

(1) Objectives Assessment of the alterations in vital signs, blood biochemical parameters and inflammatory response in patients undergoing cardiopulmonary bypass premedicated with s-medetomidine or routine anesthesia practice at Rajaei Cardiovascular and Medical Center (2) Design Randomized and double-blinded (3) Setting and conduct Patients candidate for cardiopulmonary bypass surgery were randomly assigned in two groups. Their vital signs and demographic data will be recorded. Plasma sampling will be performed in three different times, before incision, after declamping and 24 hours post-operation. ELISA method will be used for assaying IL-6, IL-8, IL-10 and TNFa markers. (4) Participants including major eligibility criteria Inclusion criteria: informed consent of guardians; weight below or equal to 15 kg; candidate for cardiopulmonary bypass surgery; Congenital heart diseases; Pump time between 1 to 3 hours; operation time between 4 and 5 hours Exclusion criteria: patients' death; active infection; operation time more than 5 hours and pump time more than 3 hours (5) Intervention 1. s-medetomidine 0.5ug/kg/hr 2. Routine anesthesia practice plus normal saline (6) Main outcome measures (variables) Blood pressure, heart rate, respiratory rate, ICU stay, mechanical ventilation time, cytokines (IL-6, IL-8, IL-10 and TNFa)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061927617N2**

Registration date: **2016-06-22, 1395/04/02**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-06-22, 1395/04/02

Registrant information

Name

Hamidreza Pazoki-Toroudi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 2708

Email address

pazoki49@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2016-07-15, 1395/04/25

Expected recruitment end date

2016-08-30, 1395/06/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of S-medtomidine infusion on pro- and anti-inflammatory cytokines in pediatric open heart surgery

Public title

Effects of S-medtomidine infusion on pro- and anti-inflammatory cytokines in pediatric open heart surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: informed consent of guardians, age

below 6, candidate for elective cardiopulmonary bypass surgery, Pump time between 1 to 3 hours; operation time between 4 and 6 hours Exclusion criteria: infection, coexisting complications, recurrent surgery, deep hypothermia, ejection fraction (EF) below 30%, patients' death; active infection; operation time more than 5 hours and pump time more than 3 hours, S-medtomidine allergy, administration of S-medtomidine one week before operation

Age

From **6 months** old to **6 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients was unaware of the treatment with s-medtomidine or placebo. Laboratory scientists measuring the serum metabolites were unaware of the study group to which the samples belong. Simple randomization will be used for allocation of participants in intervention and control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of the Iran University of Medical Sciences

Street address

Next to Milad Tower, Hemmat Highway

City

Tehran

Postal code

Approval date

2014-10-23, 1393/08/01

Ethics committee reference number

93-02-30-24854-105519

Health conditions studied

1

Description of health condition studied

congenital heart diseases

ICD-10 code

Q20-Q28

ICD-10 code description

Congenital malformations of the circulatory system

2

Description of health condition studied

Congenital malformations of cardiac septa

ICD-10 code

Q21

ICD-10 code description

Congenital malformations of cardiac septa

3

Description of health condition studied

Congenital malformations of pulmonary and tricuspid valves

ICD-10 code

Q22

ICD-10 code description

Congenital malformations of pulmonary and tricuspid valves

4

Description of health condition studied

Congenital malformations of aortic and mitral valves

ICD-10 code

Q23

ICD-10 code description

Congenital malformations of aortic and mitral valves

Primary outcomes

1

Description

IL-6

Timepoint

Before surgery, after declamp and 24 hours post ICU entrance

Method of measurement

ELISA method on plasma

2

Description

IL-8

Timepoint

Before surgery, after declamp and 24 hours post ICU entrance

Method of measurement

ELISA method on plasma

3

Description

IL-10

Timepoint

Before surgery, after declamp and 24 hours post ICU entrance

Method of measurement

ELISA method on plasma

4

Description

TNFa

Timepoint

Before surgery, after declamp and 24 hours post ICU entrance

Method of measurement

ELISA method on plasma

5

Description

Heart rate

Timepoint

every 3 hours from operation start until 24 hours post-operation

Method of measurement

Vital sign monitoring system

6

Description

blood pressure

Timepoint

every 3 hours from operation start until 24 hours post-operation

Method of measurement

Vital sign monitoring system

7

Description

respiratory rate

Timepoint

every 3 hours from operation start until 24 hours post-operation

Method of measurement

Vital sign monitoring system

Secondary outcomes

empty

Intervention groups

1

Description

Treatment group receives routine anesthesia plus s-medetomidine (0.5 ug/kg/hr)

Category

Treatment - Drugs

2

Description

Control group receives routine anesthesia plus normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaei Cardiovascular and Medical Center

Full name of responsible person

Farhad Gorjipour

Street address

Niyayesh Cross, Valiasr St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr Seyed-Ali Javad Mousavi

Street address

Next to Milad Tower, Hemmat Highway

City

Tehran

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, Iran 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

Iran University of Medical Sciences

Full name of responsible person

Fazel Gorjipour

Position

Research assistant

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