

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of corrective or palliative procedures on Arterial-End tidal CO2 pressure difference in pediatric cardiac surgery

Protocol summary

Summary

Objective: Comparing the effect procedural type on Arterial-End tidal CO2 pressure difference (DPCO2) in pediatric cardiac surgery:corrective vs. palliative Design: Non randomized clinical trial Setting and conduct: Two hundred pediatric patients up to 12 years old, candidate for elective corrective or palliative cardiac surgery enrolled to study. Anesthesia will be induced using ketamine, midazolam and cisatracurium. Using direct arterial blood gas and simultaneous capnography, DPCO2 will be measured by a coworker who is blinded to the operation type, after anesthesia induction,at immediately post procedure, ends of surgery,ICU admit and before extubation. At the end of study,patients will be classified in two corrective or palliative procedural groups and DPCO2 changes will be compared between two corrective or palliative groups at various periods. Inclusion criteria: Patients up to 12 Years old who are candidate for elective cardiac surgery Exclusion criteria: Urgent surgery; surgery; age above 12 years old Intervention: corrective or palliative cardiac surgery Outcome measures: Arterial-End tidal CO2 pressure difference

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606011127N5**

Registration date: **2016-06-07, 1395/03/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-07, 1395/03/18

Registrant information

Name

Eissa Bilehjani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Tabriz University of Medical Sciences

Expected recruitment start date

2014-09-02, 1393/06/11

Expected recruitment end date

2015-09-02, 1394/06/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of corrective or palliative procedures on Arterial-End tidal CO2 pressure difference in pediatric cardiac surgery

Public title

Comparing the effect of procedural type on Arterial-End tidal CO2 pressure difference in pediatric cardiac surgery

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Patients up to 12 Years old who are candidate for corrective or palliative elective cardiac surgery Exclusion criteria: Urgent surgery; surgery; age

above 12 years old

Age
From **1 day** old to **12 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size:

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single 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 Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Daneshgah Street, Tabriz

City
Tabriz

Postal code

Approval date
2012-03-14, 1390/12/24

Ethics committee reference number
14/7-3/90

Health conditions studied

1

Description of health condition studied
congenital heart diseases

ICD-10 code
Q24.8

ICD-10 code description
Other specified congenital malformations of heart

Primary outcomes

1

Description
arterial and end tidal carbon dioxide pressure difference

Timepoint
after anesthesia induction, immediately post procedure, ends of surgery and before extubation

Method of measurement
Simultaneous arterial blood gas analysis and capnography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Total corrective cardiac surgery

Category
Treatment - Surgery

2

Description
control group: Palliative cardiac surgery

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Madani Heart Hospital

Full name of responsible person
Eissa Bilehjani

Street address
Madani Heart Center, Daneshgah Street, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person
Mohammad Reza Rashidi

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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
Vice Chancellor for Research of Tabriz 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
empty

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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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