

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of topical and continuous infusion of Tranexamic Acid administration on bleeding in pediatric with non-cyanotic congenital heart disease

Protocol summary

Study aim

Comparison of the effect of transxamic acid(TA) administration by two methods topical and continuous infusion on the rate of hemorrhage in children with congenital non-cyanotic heart disease after open heart surgery

Design

Clinical trial with parallel groups of one-blind, accidental, phase two, 50patients

Settings and conduct

children who are candidates for surgery to close Atrial or Ventricular or Atrio-ventricular septum defect with CPB in Shahid Chamran Heart Hospital of Isfahan University of Medical Sciences in 1398, which is one-Blind and random were divided into two groups of 25 people. Continuous infusion group of 50 mg per kg of TA from induction to closing the sternum and patients of topical, 50 mg per kg of TA that reached 20 ml with normal saline solution before closing the sternum, inside Pericardium was shed and the patient's median mediastan tubules were clamped for 20 min.

Participants/Inclusion and exclusion criteria

Entry conditions for children under 14 kg and over 6 kg who are undergoing heart surgery for the first time with non-cyanotic heart disease correction with cardiopulmonary bypass(CPB), Clamp Aort time between 60 to 90 minutes and CPB time between 60 to 180 minutes and hemoglobin(HB) above 8 mg per deciliter before surgery Conditions for non-entry of HB below 8 mg per deciliter before surgery, active non-counterfeit disease affecting postoperative recovery such as severe coagulation disorders, hemophilia, etc.

Intervention groups

Prescribing TA in both topical and infusion methods to reduce bleeding

Main outcome variables

Hemoglobin changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200429047236N1**

Registration date: **2020-05-12, 1399/02/23**

Registration timing: **retrospective**

Last update: **2020-05-12, 1399/02/23**

Update count: **0**

Registration date

2020-05-12, 1399/02/23

Registrant information

Name

minoo montazeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4481 3915

Email address

minomah17@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-12, 1398/07/20

Expected recruitment end date

2020-04-08, 1399/01/20

Actual recruitment start date

2019-10-12, 1398/07/20

Actual recruitment end date

2020-03-10, 1398/12/20

Trial completion date

2020-03-10, 1398/12/20

Scientific title

Comparison of topical and continuous infusion of Tranexamic Acid administration on bleeding in pediatric with non-cyanotic congenital heart disease

Public title

Comparison of topical administration and infusion of tranexamic acid on the rate of bleeding in children with non-cyanotic heart disease after open heart surgery

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Children under 14 kg and over 6 kg For the first time, they undergo cardiac surgery to correct the aforementioned non-cyanotic diseases with cardiac bypass. Clamp aortic time between 60 to 90 minutes CPB(cardio pulmonary bypass) time between 60 to 180 minute Hemoglobin(HB) above 8 mg per deciliter before surgery Minimum age 1 month and maximum age 9 years

Exclusion criteria:

hemoglobin below 8 mg per deciliter before surgery
Active non-revolutionary disease affecting postoperative recovery such as severe coagulation disorder, hemophilia and.

Age

From **1 month** old to **9 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the census and random allocation, the samples were divided into two groups of 25 people. This randomization was performed using Random Allocation software 2.0, in which patients were assigned to one of two groups based on the number of entries in the study. This is done by a nurse outside the research team and the groups are identified as A and B. The unit of randomization is individual. Also, randomization in two groups is Balanced Block Randomization, ie the number of people in two groups is equal.

Blinding (investigator's opinion)

Single blinded

Blinding description

After obtaining informed consent from the patient's guardian (the study was performed on children), the study was one- blind side, in which only participants or patients were uninformed to the study groups, and the main staff and researchers and other colleagues who They were involved in this project, they were aware of the choice of group type, it was done.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committe of Isfahan university of medical sciences

Street address

No. 24, Baharestan 9th, Northen Janat Abad

City

Tehran

Province

Tehran

Postal code

1478777887

Approval date

2019-10-09, 1398/07/17

Ethics committee reference number

IR.MUI.MED.REC.1398.354

Health conditions studied**1****Description of health condition studied**

Diseases of Atrial and Ventricular septum defect

ICD-10 code

I51.0

ICD-10 code description

Cardiac septal defect, acquired

Primary outcomes**1****Description**

Bleeding rate in children with congenital non-cyanotic heart disease after open heart surgery

Timepoint

Upon arrival at the intensive care unit, 6, 12, 24 and 48 hours after surgery

Method of measurement

To determine the amount of bleeding, hemoglobin is measured based on arterial sampling and sent to a laboratory to measure and record arterial blood gases, and the unit is geram per deciliter.

Secondary outcomes

1

Description

Time of intubation

Timepoint

Upon arrival at the intensive care unit, 6, 12, 24 and 48 hours after surgery

Method of measurement

Hours and minute

2

Description

Intensive care unit stay

Timepoint

Upon arrival at the intensive care unit, 6, 12, 24 and 48 hours after surgery

Method of measurement

Time and minute

3

Description

Mount of derenage

Timepoint

Upon arrival at the intensive care unit, 6, 12, 24 and 48 hours after surgery

Method of measurement

According to cc

Intervention groups

1

Description

Intervention group: The first group of interventions includes patients undergoing continuous infusion of 50 mg per kg tranexamic acid from induction to sternum closure.

Category

Treatment - Drugs

2

Description

Intervention group: The second group of interventions are patients receiving topical administration of 50 mg per kg tranexamic acid, which has reached 20 ml with a normal saline solution. Before closing the sternum, it is poured into the pericardium and the patient's middle mediastan tubes are clamped for 20 minutes. (The nurse uses a sterile syringe to draw the drug into the syringe and then to a concentration of 20 ml).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran hospital in Isfahan

Full name of responsible person

Hamid Bigdelian

Street address

No. 308, Northen Alley 1th, Alikhani Ave, Mehr Ave

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1478777887

Phone

+98 31 3260 3145

Email

Hamidbigdelian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Minoo Montazeri

Street address

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Email

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Minoo Montazeri

Position

Master of science

Latest degree

Master

Other areas of specialty/work

Perfusion

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Full name of responsible person

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Position

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Latest degree

Master

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Hamid Bigdelian

Position

Head of Pediatric Cardiac Surgery and Perfusion Group

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some of the data related to the result is available.

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

All of the searchers

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Executor or person in charge of the project

What processes are involved for a request to access data/document

Contact the executor or the person in charge of the project and up to one week after the contact (contact information is mentioned.)

Comments