# 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
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No. 308, Northen Alley 1th, Alikhani Ave, Mehr Ave
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Minoo Montazeri
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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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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**