Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A clinical trial comparing the effect of topical and systemic administration of tranexamic acid versus its non-administration on bleeding volume and the need for blood products after cardiac surgery in children with congenital heart disease

Protocol summary

Study aim

To compare the effect of topical and systemic administration of tranexamic acid versus its non-administration on bleeding volume and the need for blood products after cardiac surgery in children with congenital heart disease

Design

A total of 117 patients with congenital heart disease, admitted to Vali-e-Asr Hospital in Birjand, were selected. Using a table of random numbers, the researcher assigned them to three groups, including two experimental groups and one control group, and a code was assigned to each participant.

Settings and conduct

In this double-blind trial, patient recruitment and surgery were performed in Valiasr hospital of Birjand. All patients underwent general anesthesia and surgery with the standard protocol. In the systemic group, after sternotomy, the patient was given 1 milligram per kilogram of tranexamic acid via the cardiopulmonary pump. In the topical group, after hemostasis and before sternotomy incision was closed, 1 milligram per kilogram bodyweight of tranexamic acid was dissolved in 20 mg of normal saline and poured into the pericardial cavity. The control group only received normal saline.

Participants/Inclusion and exclusion criteria

Major inclusion criteria: elective cardiac surgery; congenital heart disease; and age between one month and 15 years. Major exclusion criteria: treatment with anti-coagulants and the presence of hepatic, renal, or respiratory dysfunction.

Intervention groups

There were three groups in this study. They included the systemic group, receiving tranexamic acid systemically; the topical group, receiving tranexamic acid dissolved in normal saline into the pericardial cavity; and the control group, receiving normal saline.

Main outcome variables

Bleeding volume and need for blood products

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170316033099N11**
Registration date: **2020-02-19, 1398/11/30**
Registration timing: **retrospective**

Last update: **2020-02-19, 1398/11/30**
Update count: **0**

Registration date

2020-02-19, 1398/11/30

Registrant information

Name
Mohammad Bagher Roozgar
Name of organization / entity
Birjand University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-29, 1397/11/09

Expected recruitment end date

2019-05-30, 1398/03/09

Actual recruitment start date

2019-01-29, 1397/11/09

Actual recruitment end date

2019-05-30, 1398/03/09

Trial completion date

2019-05-30, 1398/03/09

Scientific title

A clinical trial comparing the effect of topical and systemic administration of tranexamic acid versus its non-administration on bleeding volume and the need for blood products after cardiac surgery in children with congenital heart disease

Public title

Topical and systemic administration of tranexamic acid on pediatric cardiac surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Congenital heart disease Age between one month and 15 years Elective cardiac surgery Surgery performed by one single surgeon Informed consent form signed by the patient's guardian

Exclusion criteria:

Treatment with anti-coagulants Presence of hepatic, renal, or respiratory dysfunction Low cardiac output Need for re-surgery Postoperative septicemia

Age

From **1 month** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **120**

Actual sample size reached: **117**

Randomization (investigator's opinion)

Randomized

Randomization description

After the patients were enrolled, they were allocated to one of the three study groups using a table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients and the surgeon were blinded as to which study group the patient was allocated.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Ghaffari Ave.

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2019-01-28, 1397/11/08

Ethics committee reference number

ir.bums.REC.1397.322

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

bleeding volume

Timepoint

From the completion of the surgery up to 48 hours after surgery

Method of measurement

Measurement of chest drainage volume in the chest tube

2

Description

Need for blood products including packed red blood cells, fresh frozen plasma, and platelets

Timepoint

From the completion of the surgery up to 48 hours after surgery

Method of measurement

Measurement of the packs in terms of cc

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 (systemic): After sternotomy, the patient was given 1 milligram per kilogram of tranexamic acid via the cardiopulmonary pump. Subsequently, the patient was prescribed heparin so that the activated clotting time would pass 450 seconds. At the end of the operation, after the patient was discharged from the cardiopulmonary pump, heparin was neutralized upon the administration of protamine sulfate at a dose of one mg per 100 units of heparin. Afterward, one milligram per kilogram of tranexamic acid was re-administered.

Category
Prevention

2

Description
Intervention group 2 (topical): After hemostasis and before sternotomy incision was closed, 1 milligram per kilogram bodyweight of tranexamic acid was dissolved in 20 mg of normal saline and poured into the pericardial cavity.

Category
Prevention

3

Description
Control group: They received normal saline only.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr Hospital

Full name of responsible person
Dr Mahmood Hosseinzadeh Maleki

Street address
Ghaffari Ave.

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Birjand

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HoseinzadehMalekiM@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person
Dr Tooba Kazemi

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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
Birjand 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
Birjand University of Medical Sciences

Full name of responsible person
Farbod Hatami

Position
General practitioner

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mahmood Hosseinzadeh Maleki

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Cardiology

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Person responsible for updating data

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Position
Translator

Latest degree
Master

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Others

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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
Not applicable

Title and more details about the data/document
Deidentified Individual Participant Data Set

When the data will become available and for how long
After the article extracted from the research project is published online or in print and for six months

To whom data/document is available
Readers of the article

Under which criteria data/document could be used
research purposes

From where data/document is obtainable
Personal correspondence via email to the corresponding author

What processes are involved for a request to access data/document
email to the corresponding author

Comments