Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effect of three doses of tranexamic acid on reduction of bleeding during cleft palate surgery

Protocol summary

Study aim

Determination and comparison of mean intraoperative blood loss using three doses of tranexamic acid and control group

Design

A 3 phase clinical trial with three intervention groups and one control group as parallel groups, double-blind, simple randomized by coded card selection, and a sample size of 80

Settings and conduct

In this study, 80 children in Imam Hossein Pediatric Hospital in Isfahan candidate for cleft palate surgery are included in the study and divided into four groups. Anesthesia is induced on the day of surgery after initial data recording and then the four groups receive 5 mg/kg tranexamic acid (A), 7.5 mg/kg tranexamic acid (B) and 10 mg/kg tranexamic acid (C) and placebo (D), respectively. Bleeding during surgery is accurately measured based on the amount of blood in the suction and the count of bloody gases (to calculate per gas 4 x 4 cm, 15 cc, and for larger, 30 x 30 cm, bloody gases, 50 ml of blood is considered). Surgeons' satisfaction about field of surgery is also recorded based on the Boesaart scoring system for field bleeding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Age less than 3 years 2- Class ASA I, II 3. No history of systemic disease 4- Consent to participate in this study (by parents) Exclusion criteria: 1. The operation lasts more than 3 hours 2. Incidence of surgical and anesthesia complications 3. Hypersensitivity or other contraindications to tranexamic acid use 4. History of coagulation disorders (such as hemophilia) 5. Having previous surgery in the same area 6.Children without parental consent or withholding cooperation in the project

Intervention groups

The four intervention groups receive 5 mg / kg tranexamic acid (A), 7.5 mg / kg tranexamic acid (B) and 10 mg / kg tranexamic acid (C) and placebo, normal saline (D), respectively by slow intravenous injection.

Main outcome variables

Blood volume lost

General information

Reason for update

Change intervention groups

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N26**
Registration date: **2019-12-16, 1398/09/25**
Registration timing: **prospective**

Last update: **2020-03-29, 1399/01/10**
Update count: **1**

Registration date

2019-12-16, 1398/09/25

Registrant information

Name
Sadra Ansaripour
Name of organization / entity
Shahrekord University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-30, 1399/01/11

Expected recruitment end date

2021-03-07, 1399/12/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of three doses of tranexamic acid on reduction of bleeding during cleft palate surgery

Public title

Comparison of three doses of tranexamic acid on reduction of cleft palate surgery bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age less than 3 years Has ASA class I, II No history of systemic disease Consent to participate in this study (by parents)

Exclusion criteria:

Prolonged surgery longer than 3 hours Incidence of surgical and anesthesia complications Hypersensitivity or other contraindications to tranexamic acid use A history of coagulation disorders (such as hemophilia) Prior surgery in the same area Children without parental consent or withholding of participation in the project

Age

To **3 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize the study, simple randomization with individual unit is used, so that patients randomly select one of the cards containing the codes A or B or C so they enter one of the three treatment groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Since the treatments are different doses, the drugs will be prepared at the desired doses and will be indicated in packages with codes A, B and C; To ensure that the registrant of patients information and the surgeon does not have any awareness of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahn University of Medical Sciences, Hezar jarib st, Isfahan

City

Isfahan

Province

Isfehan

Postal code

7346181746

Approval date

2019-05-11, 1398/02/21

Ethics committee reference number

IR.MUI.MED.REC.1398.057

Health conditions studied

1

Description of health condition studied

Intraoperative bleeding in cleft palate surgery

ICD-10 code

ICD-10 code description

blood loss

Primary outcomes

1

Description

The volume of blood lost

Timepoint

During operation

Method of measurement

Check list

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: One group of patients undergoing cleft palate surgery after induction of anesthesia received 5 mg / kg tranexamic acid by slow intravenous injection.

Category

Treatment - Drugs

2

Description
Second intervention group: One group of patients undergoing cleft palate surgery after induction of anesthesia received 7.5 mg / kg tranexamic acid by slow intravenous injection.
Category
Treatment - Drugs

3

Description
Third intervention group: One group of patients undergoing cleft palate surgery after induction of anesthesia received 10 mg / kg tranexamic acid by slow intravenous injection.
Category
Treatment - Drugs

4

Description
Control group: One group of patients undergoing cleft palate surgery after induction of anesthesia received normal saline as placebo by slow intravenous injection.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
In Imam Hossein Pediatric Hospital, Isfahan
Full name of responsible person
Amir Shafa
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ziba Farajzadegan
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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
Amir Shafa
Position
Professor of Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
No - There is not 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
Information about the main outcome can be shared.
When the data will become available and for how long
Start the access period 4 months after publishing the results
To whom data/document is available
Researchers working in academia
Under which criteria data/document could be used
Use data to complete clinical trial studies
From where data/document is obtainable
Imam Hussein Hospital
What processes are involved for a request to access data/document
After the investigation of the researcher request and presentation of required documents will be accessible.
Comments