

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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 Ansari pour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 3487

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st_ansari.s@skums.ac.ir

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

Isfahan

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

Imam Hossein Hospital

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7346181746

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+98 31 3445 2031

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amir_shafa@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

Street address

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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

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Other areas of specialty/work

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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