Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of local injection of tranexamic acid on bleeding during surgery in patients with cleft palate

Protocol summary

Study aim
Comparison of the effectiveness of local injection of tranexamic acid in the amount of bleeding during surgery in patients with cleft palate in two intervention and control groups referring to Hazrat Fatemeh Teaching Hospital and Moheb Kausar and Parsian Hospitals in Tehran.

Design
The clinical trial has two control and intervention groups with parallel groups, the study will be two-sided and randomized by lottery between 24 patients and 12 patients in each group.

Settings and conduct
This study is a double-blind randomized clinical trial, the surgeon and the patients are unaware of the type of intervention. To conduct this study randomly, patients are placed in two intervention groups and control group . After obtaining informed consent from the applicant patients, for the intervention group, the drug (tranexamic acid) was prepared for the patient half an hour before the operation, topically along with normal solution. Saline, epinephrine and lidocaine are injected. For the control group, only normal saline solution, epinephrine and lidocaine are injected. This study is carried out in Hazrat Fatemeh, Moheb Kausar and Parsian hospitals.

Participants/Inclusion and exclusion criteria
Children between 8 to 60 months Cleft palate alone Without having diseases such as heart arrhythmia or blood sugar

Intervention groups
Two control and intervention groups, each of which will have 12 patients. For the intervention group, the prepared medicine (10 mg/kg tranexamic acid) is injected locally to the patient half an hour before the operation along with 1 normal saline solution in 200,000 epinephrine and 5 mg/kg lidocaine, and for the control group only normal saline solution 1 in 200,000 epinephrine and lidocaine 5 mg/kg are injected.

Main outcome variables
Duration of surgery, intraoperative bleeding, surgeon satisfaction, intraoperative side effects

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230424057979N1**
Registration date: **2023-05-01, 1402/02/11**
Registration timing: **prospective**

Last update: **2023-05-01, 1402/02/11**
Update count: **0**

Registration date
2023-05-01, 1402/02/11

Registrant information
Name
Mahdi Karami
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-05-05, 1402/02/15
Expected recruitment end date
2023-08-06, 1402/05/15
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of local injection of tranexamic acid on bleeding during surgery in patients with cleft palate

Public title

Evaluation of the effect of local injection of tranexamic acid on bleeding during surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children between 8 to 60 months Cleft Palate

Exclusion criteria:

Cleft Lip

Age

From **8 months** old to **60 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

To conduct this study randomly, patients are placed in two intervention groups (12 people) and control group (12 people). The randomization in this study is such that we have a 24 envelope of two letters A (12 pieces) and B (12 pieces), where the letter A represents the intervention group and the letter B represents the control group (without tranexamic acid). which is taken out of a paper envelope for each patient before the surgery, and according to the words on it, they will be assigned to one of the two groups and will be operated on. The assistant or the person who opens the envelope will prepare the tranexamic acid solution when the surgeon is not present before the operation and it will be used by the surgeon during the operation.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and surgeons are unaware of the use of tranexamic acid. The method of blinding the surgeon is that the surgical assistant or anesthesiologist fills a syringe with this substance before the surgeon enters the operating room and injects it locally as an anesthetic with normal saline before the operation, and the surgeon injects the substance The inside of the syringe is uninformed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-04-19, 1402/01/30

Ethics committee reference number

IR.IUMS.FMD.REC.1402.038

Health conditions studied

1

Description of health condition studied

Cleft Palate

ICD-10 code

Q35

ICD-10 code description

Cleft palate

Primary outcomes

1

Description

The amount of bleeding during surgery

Timepoint

During surgery

Method of measurement

Quantitative criterion (the result of the difference in the weight of the accumulations of the suction glasses and the volume of the solution used for washing) and cumulative bleeding in gas pellets (the result of the difference in the weight of blood gases from the weight of the same amount of dry gas) and the qualitative Boezaart criterion

Secondary outcomes

1

Description
Surgeon satisfaction
Timepoint
After Surgery
Method of measurement
By Likert scale

Intervention groups

1

Description
Intervention group: the prepared medicine (10 mg/kg tranexamic acid) is injected locally to the patient half an hour before the operation along with 1 normal saline solution in 200,000 epinephrine and 5 mg/kg lidocaine.
Category
Treatment - Drugs

2

Description
Control group: only normal saline solution 1 in 200,000 epinephrine and lidocaine 5 mg/kg are injected
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrate Fatemeh Hospital
Full name of responsible person
Abbas Kazemi Ashtiani
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2

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Name of recruitment center
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3

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Hazrate Fatemeh Hospital
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
Iran University of Medical Sciences
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Mahdi Karami
Position
Specialist Assistant
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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
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
The data of the participants, the study protocol and its clinical report can be presented to the referents in the form of a thesis bound in the central library of the University of Medical Sciences and the library of Hazrat Fatemeh Hospital.
When the data will become available and for how long
The clinical protocol and report will be accessible whenever the libraries are visited.
To whom data/document is available
Referees to Hazrat Fatima Library and people who are members of the Central Library of Iran University of Medical Sciences.
Under which criteria data/document could be used
In order to model the implementation method or get ideas for future studies, the documentation of this research can be used

From where data/document is obtainable

Hazrat Fatemeh Hospital Library located in Yusuf Abad

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

Call Hazrat Fatimah Hospital and request to receive documents and then arrange to visit in person.

Comments