

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8871 7272

##### Email address

dr.m.karami@gmail.com

##### 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

##### **Street address**

Seyed Jamalodin Asadabadi St.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1433933111

##### **Phone**

+98 21 8871 7272

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akazemia2003@gmail.com

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Moheb Kowsar Hospital

##### **Full name of responsible person**

Abbas Kazemi Ashtiani

##### **Street address**

Seyed Jamalodin Asadabadi St.

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akazemia2003@gmail.com

### 3

#### **Recruitment center**

##### **Name of recruitment center**

Parsian Hospital

##### **Full name of responsible person**

Abbas Kazemi Ashtiani

##### **Street address**

Saadat abad

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1998653651

##### **Phone**

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##### **Email**

akazemia2003@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Iran University of Medical Sciences

##### **Full name of responsible person**

Hossein Keyvani

##### **Street address**

Iran University of Medical Sciences

##### **City**

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##### **Province**

Tehran

##### **Postal code**

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##### **Phone**

+98 21 8670 2504

##### **Email**

keyvani.h@iums.ac.ir

#### **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

**Full name of responsible person**

Mahdi Karami

**Position**

Specialist Assistant

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Abbas Kazemi Ashtiani

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Plastic and Reconstructive Surgery

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**Email**

akazemia2003@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mahdi Karami

**Position**

Specialist assistant

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Plastic and Reconstructive surgery

**Street address**

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**Province**

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**Fax****Email**

dr.m.karami@gmail.com

**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**