

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of topical tranexamic acid injection on bleeding during and after tonsillectomy in patients aged 15 to 45 years

Protocol summary

Study aim

Determining and comparing the average volume of bleeding and the incidence of rebleeding on the side of the tonsil receiving tranexamic acid and on the side of the tonsil receiving placebo during surgery and recovery
Determining and comparing the average score of the surgeon's satisfaction on the side of the tonsil receiving tranexamic acid and the side of the tonsil receiving placebo
Determining and comparing the average duration of surgery in the tonsillar side receiving tranexamic acid and the tonsil side receiving placebo

Design

Clinical trial with control group with single group, double-blind, randomized, phase 2 on 20 randomized patients using randomization software

Settings and conduct

Operating room of Al-Zahra and Kashani hospitals in Isfahan

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients aged 15 to 45 years who are candidates for tonsillectomy with functional status 1 and 2 according to the criteria of the American Society of Anesthesiologists (ASA) and informed consent to participate in the study. Exclusion criteria :
contraindication of tranexamic consumption for any reason including drug allergy, use of anticoagulants by the patient, hematological diseases (hemolytic disease, hemoglobinopathies, coagulopathy and thromboembolic events), uncontrolled systemic diseases, patient dissatisfaction and cauter is used to control bleeding during surgery.

Intervention groups

Tranxamic acid is injected randomly into the bed of the right or left tonsil. Intraoperative bleeding for each side of the tonsils up to 24 hours after surgery. The surgeon's satisfaction is assessed. In each patient, distilled water will be injected into the tonsils on the opposite side, which is considered as control.

Main outcome variables

Bleeding rate; Moderate arterial blood pressure; heart beat; Surgeon Satisfaction; Duration of Surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211028052900N2**

Registration date: **2022-05-01, 1401/02/11**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-01, 1401/02/11**

Update count: **0**

Registration date

2022-05-01, 1401/02/11

Registrant information

Name

Maryam Fatahinasab

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3626 3176

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rezamdmr70@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-03, 1401/01/14

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of topical tranexamic acid injection on bleeding during and after tonsillectomy in patients aged 15 to 45 years

Public title

The effect of topical tranexamic acid injection on bleeding during and after tonsillectomy in patients aged 15 to 45 years

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

15 to 45 years old Functional class 1 and 2

Exclusion criteria:

contraindication of the use of tranexamic acid for any reason, including allergies to the drug Anticoagulants consumption Hematologic disorders Uncontrolled systemic diseases Use a catheter to control bleeding during surgery

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method is a simple randomization that is done by statistical software. The list of patients under study is prepared in advance, which includes 20 people. 10 people are supposed to be injected on the right side and 10 people on the left side, and in each of them placebo will be injected in the opposite side. Then, using random allocation software, 10 people are randomly placed in the right group and 10 people in the left group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The main surgeon is blind to assigning the study group. The assistant surgeon injects tranexamic acid into a patient's tonsil bed and injects distilled water into the opposite side, and the primary surgeon is unaware of the injection of tranexamic acid. The patient will not be informed of the side where the tranexamic acid was injected.

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 Science

Street address

Isfahan , Hezarjarib ave

City

Isfahan

Province

Isfahan

Postal code

73461-81746.

Approval date

2022-03-02, 1400/12/11

Ethics committee reference number

IR.MUI.MED.REC.1400.821

Health conditions studied**1****Description of health condition studied**

TONSILECTOMY

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

amount of bleeding during tonsillectomy

Timepoint

24 hour after surgery

Method of measurement

The amount of blood collected in the suction and the change in weight of the soaked gas

Secondary outcomes**1****Description**

Surgeon satisfaction

Timepoint

after surgery

Method of measurement

Scale one to ten

Intervention groups

1

Description

Intervention group: 10 minutes before surgery, 100 mg of tranexamic acid is injected randomly into the bed of the right or left tonsil. The amount of intraoperative bleeding is calculated for each side of the tonsils (based on the volume of blood inside the calibrated suction and the difference in weight of blood gases before and after use, which is considered the difference in weight equal to 1 cc of blood per gram. Recovery for each side of the tonsils is performed up to 24 hours after the operation by a nursing expert who was unaware of the type of intervention drug in the patient. The score is evaluated from 0 to 10. The lowest satisfaction score is zero and the highest satisfaction score is 10 (obtained for each side of the tonsils separately). The type of surgical technique performed for all patients is cold dissection and homeostasis by suture.

Category

Treatment - Drugs

2

Description

Control group: An equal volume of distilled water is injected into the opposite side of the tonsil and the amount of bleeding during the operation for each side of the tonsil (based on the volume of blood inside the calibrated suction and the difference in weight of blood gases before and after use. Blood is considered to be calculated, and also the occurrence of bleeding in the recovery for each side of the tonsils up to 24 hours after the operation is done by a nursing expert who was unaware of the type of intervention drug in the patient. It is deducted from the volume inside the suction device. The surgeon's satisfaction is evaluated based on a score from 0 to 10, which will have the lowest satisfaction score of zero and the highest satisfaction score of 10 (which is obtained for each side of the tonsils separately). Surgery is performed for all patients with cold dissection and homeostasis by suture.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

alzahra hospital

Full name of responsible person

Ali badrooj

Street address

sofe bolved

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isfahan

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81746-75731

Phone

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Email

alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

dr mansour siavash dastjerdi

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research@mui.ac.ir

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

ali badrooj

Position

medical resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentifiable individuals.

When the data will become available and for how long

Start of access period 1 month after printing the results

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Statistical analysis and the use of anonymous and unidentifiable documents will be possible after obtaining permission from the study researchers, provided by email.

From where data/document is obtainable

It is possible to access the studies by email or by contacting the responsible researcher, Ali Badrouj. abadrooj@gmail.com 00989140814990

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

After submitting the request to the responsible researcher, he / she will consult with other researchers and after obtaining the opinions of other researchers, the applicant will be answered within 1 week.

Comments