Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 transexamic 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)

Phone

+98 31 3626 3176

Email address

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 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
Isfehan

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
City
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Province
Isfehan
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81746-75731
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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
Street address
hezarjarib avenue
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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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Medical doctor

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Person responsible for updating data

Contact

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Position
medical resident

Latest degree
Medical doctor

Other areas of specialty/work
Ear, Nose, and Throat

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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