Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of topical tranexamic acid in level of bleeding during and after tonsillectomy surgery

Protocol summary

Study aim
Investigating the effect of topical tranexamic acid on the amount of bleeding during and after tonsillectomy surgery

Design
The clinical trial will have a control and intervention group, in parallel and double-blind trial, randomized by a simple randomization method using a closed envelope and a phase 2-3 clinical trial study on 60 patients.

Settings and conduct
The study will be conducted on 60 patients referred to Ghaim Hospital (AJ) in Mashhad who are candidates for tonsillectomy surgery, which are placed in the intervention and control groups in a parallel double-blind trial (participant, evaluators). In the intervention group, tranexamic acid will be injected intravenously, and in the control group, normal saline will be injected during surgery. The effect of intervention on the amount of bleeding in two groups will be compared.

Participants/Inclusion and exclusion criteria
The main condition for entering the study is the informed consent of the patient and the need to perform tonsillectomy surgery, and the absence of bleeding diseases, the presence of non-relative hypertrophy of the tonsils, and the absence of a history of sensitivity to tranexamic acid.

Intervention groups
In the intervention group, tranexamic acid (5 ml vial of tranexamic acid 100mg/ml) is injected locally into the tonsils on both sides of the anterior pillar during surgery. In the control group, a 5 ml vial of normal saline is injected locally into the patient's tonsils during surgery.

Main outcome variables
The amount of bleeding based on suctioned blood volume and gas pack

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210923052559N3**
Registration date: **2023-11-22, 1402/09/01**
Registration timing: **prospective**

Last update: **2023-11-22, 1402/09/01**
Update count: **0**

Registration date
2023-11-22, 1402/09/01

Registrant information

Name
Farzaneh Iravani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3723 1750

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farzaneh.baroon@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-10, 1402/09/19

Expected recruitment end date
2024-03-09, 1402/12/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of topical tranexamic acid in level of bleeding during and after tonsillectomy surgery

Public title
Investigating the effect of tranexamic acid on tonsillectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent of the patient Patients who are candidates for tonsillectomy surgery
Exclusion criteria:
Suffering from bleeding diseases The presence of tonsillar hypertrophy History of sensitivity to tranexamic acid Abnormal bleeding from the adenoid during surgery Taking drugs that may increase bleeding, such as aspirin
Age
From **5 years** old to **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization will be done by www.randomization.com website . Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study subjects and those who evaluate the outcome in the participants will be unaware of the intervention and control groups due to the fact that the placebo is used in the study in parallel with the drug
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2023-09-18, 1402/06/27
Ethics committee reference number
IR.MUMS.IRH.REC.1402.127

Health conditions studied

1

Description of health condition studied
Haemorrhage due to tonsillectomy surgery
ICD-10 code
Y60
ICD-10 code description
Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care

Primary outcomes

1

Description
The amount of bleeding
Timepoint
During surgery, 24 hours and one week after surgery
Method of measurement
The amount of bleeding is calculated based on the amount of suctioned blood and gas pack. The blood volume of each small gas of 10 x 10 cm size is considered to be about 12 cc, the blood volume in the suction tube is also evaluated.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, immediately at the beginning of the tonsillectomy procedure, trangesamic acid (a 5 ml vial of trangesmic acid 100 mg/ml) will be injected at the dose of 10 mg/kg to the tonsils of the patients. In each patient, the injection in the anterior pillar will be done once in the upper, middle and lower part.
Category
Treatment - Surgery

2

Description
Control group: In the control group, normal saline (in the

same vials with tranexamic acid with 5 ml volume) will be injected into the tonsils of the patients at the beginning of the tonsillectomy procedure. The injection in the anterior pillar will be done once in the upper, middle and lower part.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem hospital

Full name of responsible person
Imaneh Roshanzamir

Street address
Ghaem hospital, Ahmad Abad Ave

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9176699199

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr Majid Ghayour Mobarhan

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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Imaneh Roshanzamir

Position
Associate professor

Latest degree
Specialist

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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Person responsible for updating data

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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available