

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)

Phone

+98 51 3723 1750

Email address

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

Phone

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Email

roshanzamiri@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Majid Ghayour Mobarhan

Street address

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

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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