

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Assesment of the effect of tranexamic acid on perioperative bleeding in patients undergoing adenotonsillectomy

Protocol summary

Study aim

Determining of the effect of tranexamic acid on perioperative bleeding in patients undergoing adenotonsillectomy

Design

A randomized clinical trial on 160 patients with control group, society based and pragmatic, single blinded

Settings and conduct

After IV line taking, 5ml/kg crystalloid fluid, 0.05mg/kg midazolam and 1µg/kg remifentanil will be injected. the general anesthesia will be inducted by 5mg/kg sodium thiopental and 0.6mg/kg atracurium for intubation faciliation. one group will receive 10ml/Kg tranexamic acid ampule stat before surgery but other group wont receive it. The patients don't know if they receive it or not. the patients will be moved to ward when the pain be stopped or reduced, and bleeding stopped with no nausea and vomiting. all patients will be survived in hospital for 24h after surgery. The bleeding volume will be evaluated with scaling serum and blood mixture in suction glass. Generally the used serum will be deducted from mixture volume and blood volume will be identified. Data collecting tool is information forms which includes demographics and study variables.

Participants/Inclusion and exclusion criteria

Patient will be selected from tonsilectomy candidates ages 6months to 14years old. We used simple selection according to inclusion and exclusion criteria after urine analysis for hematuria rule out.

Intervention groups

The tonsilectomy indicated patients ages 6 months to 14 years old who were referred to ENT clinic of khatamolanbia hospital of zahedan in 2017

Main outcome variables

tran examic acid; prevention; bleeding; control; anemia; surgery; tonsilectomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180404039191N1**

Registration date: **2018-04-30, 1397/02/10**

Registration timing: **retrospective**

Last update: **2018-04-30, 1397/02/10**

Update count: **0**

Registration date

2018-04-30, 1397/02/10

Registrant information

Name

behnam shamsodin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5744

Email address

b.shamsaddin@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-11, 1396/12/20

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2018-01-21, 1396/11/01

Trial completion date

empty

Scientific title

Assesment of the effect of tranexamic acid on perioperative bleeding in patients undergoing adenotonsillectomy

Public title

Assesment of the effect of tranexamic acid on perioperative bleeding in patients undergoing adenotonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Normal U/A Recurrent tonsillitis Chronic tonsillitis Sleep obstructive apnea syndrome Tonsillar hypertrophy Dysphagia

Exclusion criteria:

Allergy to tranexamic acid Hematuria history Patients disagreement to attend in study

Age

From **6 months** old to **14 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **160**

Actual sample size reached: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients randomly be divided into two groups of 6 blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients dont know if they had received medicine or placebo

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic comittee of Zahedan University of Medical Sciences

Street address

Dr Hesabi Square.Zahedan University of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2017-05-25, 1396/03/04

Ethics committee reference number

ir.zaums.rec.1396.344

Health conditions studied

1

Description of health condition studied

Adenoid

ICD-10 code

J35.2

ICD-10 code description

Hypertrophy of adenoids and Enlargement of adenoids

Primary outcomes

1

Description

The bleeding volume which is evaluated in first 24h after surgery.

Timepoint

First 24h after surgery

Method of measurement

Graduated cylinder

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who received tran examic acid: After IV line taking, 5ml/kg crystaloid fluid, 0.05mg/kg midazolam and 1µg/kg remifentanil will be injected. The general anesthesia will be inducted by 5mg/kg sodium thiopental and 0.6mg/kg atracurium for intubation faciliation. One group will receive 10ml/Kg tranexamic acid ampule stat before surgery.

Category

Treatment - Drugs

2

Description

Control group: Patients who received distilled water as placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

ENT clinic of Khatamolanbia hospital of Zahedan

Full name of responsible person

Behnam Shamsaddin

Street address

Begining of Jamejam Avenue, Zahedan

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Gholamali Dashty Khavidki

Street address

Dr Hesabi Square, Zahedan University of Medical Sciences

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Behnam Shamsadin

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Ear, Nose, and Throat

Street address

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

According to ethics rules of Zahedan medical university for patients data privacy

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available