Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

Study aim
Determining of the effect of tranexamic acid on perioperative bleeding in patients undergoinig 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 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 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 undergoinig adenotonsillectomy

Public title
Assesment of the effect of tranexamic acid on perioperative bleeding in patients undergoinig adenotonsillectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Normal U/A Recurrent tonsilitis Chronic tonsilitis Sleep obstructive apnea syndrome Tonsilar 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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b.shamsaddin@zaums.ac.ir

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
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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)
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