Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effect of two doses of tranexamic acid on intraoperative hemodynamic changes in patients undergoing adenotonsillectomy

Protocol summary

Study aim
Comparison of the effect of two doses of tranexamic acid on intraoperative hemodynamic changes in patients undergoing adenotonsillectomy

Design
A clinical trial without a parallel control group, double-blind, randomized

Settings and conduct
This study is performed at Imam Hossein Children's Hospital. After premedication, patients with midazolam 0.1 mg / kg are separated from their parents and brought to the operating room. They were then anesthetized with 2µg / kg fentanyl, 5mg / kg thiopental sodium and 0.5mg / kg atracurium, intubated with the appropriate size, attached to the ventilator, and anesthetized with 1% isoflurane. Patients were then randomly divided into two groups of 32 according to the random number table. One group received 5mg / kg tranexamic acid for 10 minutes and another group received 10mg / kg tranexamic acid for 10 minutes.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children aged 5 to 10 years are candidates for ASAI, ASAI adenotonsillectomy; Exclusion criteria: any underlying disease, bleeding disorders, impaired coagulation tests (PT, PTT, INR) and metabolic disorders.

Intervention groups
The first group received 5mg / kg tranexamic acid and the second group received 10mg / kg tranexamic acid.

Main outcome variables
Mean arterial pressure; Heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171030037093N33**
Registration date: **2020-03-27, 1399/01/08**
Registration timing: **prospective**

Last update: **2020-03-27, 1399/01/08**
Update count: **0**

Registration date
2020-03-27, 1399/01/08

Registrant information

Name
Sadra Ansaripour

Name of organization / entity
Shahrekord University of Medical Sciences

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Iran (Islamic Republic of)

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st_ansari.s@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-03, 1399/01/15

Expected recruitment end date
2021-03-25, 1400/01/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the effect of two doses of tranexamic acid on intraoperative hemodynamic

changes in patients undergoing adenotonsillectomy

Public title
Comparison of the effect of two doses of tranexamic acid on hemodynamic changes in patients
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 5 to 10 years are candidates for ASAI, ASAI adenotonsillectomy.
Exclusion criteria:
The patient has any underlying disease The patient has bleeding disorders Patient with coagulation disorders (PT, PTT, INR) The patient has metabolic disorders
Age
From **5 years** old to **10 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
The study sample was simple randomly divided into two groups of 32 people, each by selective envelopes. Thus, each envelope containing one of the two A and B labels represented one of the groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The blinding method is that the drugs are drawn and coded by the researcher in equal volumes on the same syringes. The prescribing anesthetist and the nurse recorder are not aware of the patients' placement in the groups.
Placebo
Not 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 Sciences
Street address
Isfahn University of Medical Sciences, Hezar jarib st, Isfahan
City
Isfahan
Province
Isfehan
Postal code
7346181746
Approval date
2020-02-29, 1398/12/10
Ethics committee reference number
IR.MUI.MED.REC.1398.639

Health conditions studied

1

Description of health condition studied
Hemodynamic changes
ICD-10 code
R03
ICD-10 code description
Abnormal blood-pressure reading, without diagnosis

Primary outcomes

1

Description
Mean arterial pressure
Timepoint
Before induction and during anesthesia every 15 minutes
Method of measurement
Mercury barometer

2

Description
Pulse rate
Timepoint
Before induction and during anesthesia every 15 minutes
Method of measurement
Pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: First group receive 5mg / kg tranexamic acid from Caspian Pharmaceutical Company intravenously and slowly once during 10 minutes before surgery.
Category
Treatment - Drugs

2

Description

Intervention group 2: Second group receive 10 mg / kg tranexamic acid from Caspian Pharmaceutical Company intravenously and slowly once during 10 minutes before surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

In Imam Hossein Pediatric Hospital, Isfahan

Full name of responsible person

Amir Shafa

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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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

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

Amir Shafa

Position

Associate Professor of Anesthesiology

Latest degree

Specialist

Other areas of specialty/work

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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
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