# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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

**Country**
Iran (Islamic Republic of)

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+98 31 3650 3487

**Email address**
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

**Street address**

Imam Hossein Hospital

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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**

Anesthesiology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**
Associate Professor of Anesthesiology

**Latest degree**
Specialist

**Other areas of specialty/work**
Anesthesiology

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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