

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparison the efficacy of different doses of tranexamic acid on amount of bleeding and duration of surgery in sinus endoscopy

#### Protocol summary

##### Summary

The aim of this study is the comparison of two doses of tranexamic acid on bleeding duration of surgery and satisfaction of surgeon in sinus endoscopy. Inclusion criteria: all patients 16 to 60 years old with ASA I,II are undergoing sinus endoscopy with no airway complications, systemic diseases or known psychological diseases surgery patients had no history of sensitivity to anesthesia or any other drugs used in this study. Exclusion criterion: the time of operation takes more than 150 minutes. Hundred patients are randomly divided into two groups; the first group, receive 5mg/kg tranexamic acid and the second group receive 10 mg/kg tranexamic acid then systolic and diastolic blood pressure, heart rate measured in 15, 30, 60, 90, 120, 150 minutes, Satisfaction of surgeon, time of surgery and bleeding volume and side effects of drug are recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015062021436N2**

Registration date: **2015-07-07, 1394/04/16**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-07-07, 1394/04/16

##### Registrant information

##### Name

Shideh Marzban

##### Name of organization / entity

Guilan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3727 1717

##### Email address

sh\_marzban@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Guilan University of Medical Sciences

##### Expected recruitment start date

2015-07-23, 1394/05/01

##### Expected recruitment end date

2015-11-22, 1394/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the efficacy of different doses of tranexamic acid on amount of bleeding and duration of surgery in sinus endoscopy

##### Public title

The efficacy of different doses of tranexamic acid on amount of bleeding and duration of surgery in sinus endoscopy

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: all patients 16 to 60 years old with ASA I,II are undergoing sinus endoscopy with no airway complications, systemic diseases or known psychological diseases surgery Patients had no history of sensitivity to anesthesia or any other drugs used in this study. Exclusion criterion: the time of operation takes more than 150 minutes.

##### Age

From **16 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Guilan University of Medical Sciences

**Street address**

Shahid Beheshti Freeway

**City**

Rasht

**Postal code**

4193833697

**Approval date**

2015-06-09, 1394/03/19

**Ethics committee reference number**

IR.GUMS.REC.1394.49

**Health conditions studied****1****Description of health condition studied**

Bleeding, sinus

**ICD-10 code**

O46.9

**ICD-10 code description**

Antepartum haemorrhage, unspecified

**Primary outcomes****1****Description**

Bleeding

**Timepoint**

15, 30, 60, 90, 120 and 150 minutes after surgery

**Method of measurement**

Boezaart scale

**2****Description**

Duration of surgery

**Timepoint**

At the end of surgery

**Method of measurement**

Minute

**3****Description**

Surgeon satisfaction

**Timepoint**

At the end of surgery

**Method of measurement**

Likertt scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

First group:infusion of 5mg/kg tranexamic acid

**Category**

Prevention

**2****Description**

Second group :infusion of 10mg/kg tranexamic acid

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Amir Al-Momenin

**Full name of responsible person**

Shideh Marzban

**Street address**

Fifteenth Khordad Street

**City**

Rasht

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research of Guilan University of  
Medical Sciences

**Full name of responsible person**

Abtin Heidarzadeh

**Street address**

Shahid Beheshti Freeway

**City**

Rasht

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research of Guilan University of  
Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Person responsible for scientific  
inquiries**

**Contact**

**Name of organization / entity**

Guilan University of Medical Science

**Full name of responsible person**

Shideh Marzban

**Position**

Anesthesiologist

**Other areas of specialty/work**

**Street address**

Amir Al-momenin Hospital

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Hedyeh Nemati

**Position**

Medical laboratory Sciences Technician/ Bachelor's  
Degree

**Other areas of specialty/work**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*