Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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