

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of intravenous Tranexamic acid on blood loss and the quality of surgical field during endoscopic sinus surgery: A placebo-controlled clinical trial

Protocol summary

Summary

Objectives: To evaluate the effect of intravenous tranexamic acid on blood loss and the quality of surgical field in functional endoscopic sinus surgery. Methods: In a placebo-controlled clinical trial a total of 84 ASA physical status I-II patients, aged 19–64 years, undergoing endoscopic sinus surgery for chronic sinusitis were randomly allocated to receive either intravenous TA 10 mg/kg or sterile water 0.1cc/kg as a bolus dose immediately after induction of anesthesia. Anesthesia and surgery protocols were the same in both groups. The amount of blood loss as well as bleeding and satisfaction scores obtained from the surgeon were measured and compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010265026N1**

Registration date: **2011-02-21, 1389/12/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-02-21, 1389/12/02

Registrant information

Name

Masood Mohseni

Name of organization / entity

Rasul Akram hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6435 2326

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Recruitment status

Recruitment complete

Funding source

Vice chanceller for research, Tehran University of Medical Sciences

Expected recruitment start date

2009-04-01, 1388/01/12

Expected recruitment end date

2010-10-30, 1389/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intravenous Tranexamic acid on blood loss and the quality of surgical field during endoscopic sinus surgery: A placebo-controlled clinical trial

Public title

The effect of intravenous Tranexamic acid on blood loss and the quality of surgical field during endoscopic sinus surgery

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion: ASA physical status I-II patients candidate of endoscopic sinus surgery for chronic sinusitis Exclusion: Patients receiving anticoagulants or having a bleeding diathesis

Age

From **19 years** old to **64 years** old

Gender

Both	Standardized scale
Phase 3	2
Groups that have been masked No information	Description Blood loss
Sample size Target sample size: 84	Timepoint at the end of surgery
Randomization (investigator's opinion) Randomized	Method of measurement visual estimation of blood loss in bottles
Randomization description	
Blinding (investigator's opinion) Double blinded	
Blinding description	
Placebo Used	
Assignment Parallel	
Other design features	
Secondary Ids empty	Secondary outcomes
	1
	Description blood pressure, heart rate
	Timepoint q 15 minutes
	Method of measurement data collected from standard operating room monitoring systems
Ethics committees	Intervention groups
1	1
Ethics committee Name of ethics committee Ethics committee of Tehran University of Medical Sciences Street address Hemmat Blv City Tehran Postal code	Description intravenous tranexamic acid (10 mg/kg as a bolus dose immediately after induction of anesthesia) Category Treatment - Drugs
Approval date 2009-05-24, 1388/03/03	2
Ethics committee reference number 861 پ	Description Placebo (sterile water 0.1cc/kg as a bolus dose immediately after induction of anesthesia) Category Placebo
Health conditions studied	Recruitment centers
1	1
Description of health condition studied Haemorrhagic condition	Recruitment center Name of recruitment center Rasul Akram Hospital Full name of responsible person Street address City Tehran
ICD-10 code D69.9	
ICD-10 code description Haemorrhagic condition, unspecified	
Primary outcomes	Sponsors / Funding sources
1	1
Description The quality of surgical field	Sponsor Name of organization / entity Vice chancellor for Research, Tehran University of Medical Sciences
Timepoint at the end of surgery	
Method of measurement	

Full name of responsible person

Masoud Younesian

Street address

N 601, 6th floor, Tehran University of Medical Sciences, Ghods Ave, Keshavarz Blv

City

Tehran

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, Tehran 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****Name of organization / entity**

Department of Anesthesiology, Tehran University of Medical Sciences

Full name of responsible person

Mahzad Alimian

Position

Assistant professor

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Resident of Anesthesiology

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Web page address**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