

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 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)

Phone

+98 21 6435 2326

Email address

mohseni@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor 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

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 84

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Hemmat Blv

City

Tehran

Postal code

Approval date

2009-05-24, 1388/03/03

Ethics committee reference number

861 پ

Health conditions studied

1

Description of health condition studied

Haemorrhagic condition

ICD-10 code

D69.9

ICD-10 code description

Haemorrhagic condition, unspecified

Primary outcomes

1

Description

The quality of surgical field

Timepoint

at the end of surgery

Method of measurement

Standardized scale

2

Description

Blood loss

Timepoint

at the end of surgery

Method of measurement

visual estimation of blood loss in bottles

Secondary outcomes

1

Description

blood pressure, heart rate

Timepoint

q 15 minutes

Method of measurement

data collected from standard operating room monitoring systems

Intervention groups

1

Description

intravenous tranexamic acid (10 mg/kg as a bolus dose immediately after induction of anesthesia)

Category

Treatment - Drugs

2

Description

Placebo (sterile water 0.1cc/kg as a bolus dose immediately after induction of anesthesia)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasul Akram Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Tehran University of Medical Sciences

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

Other areas of specialty/work**Street address**

Department of Anesthesiology, Rasul Akram Hospital

City

Tehran

Postal code**Phone**

+98 216432326

Fax**Email**

Alimian.mahzad@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mahzad Alimian

Position

assistant professor

Other areas of specialty/work**Street address**

Department of Anesthesiology, Rasul Akram hospital

City

Tehran

Postal code**Phone**

+98 21 6435 2326

Fax**Email**

alimian.mahzad@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Masood Mohseni

Position

Resident of Anesthesiology

Other areas of specialty/work**Street address****City****Postal code****Phone****Fax****Email**

masood.mohseni@gmail.com

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*