Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the Effects of Two Doses of Intravenous Tranexamic Acid on Blood loss and Feild of the surgery during Endoscopic Sinus Surgery

Protocol summary

Summary

This study planed to compare the effects of two doses of intravenous tranexamic acid on amount of bleeding and quality of the field of the surgery during endoscopic sinus surgery. After Ethics Committee approval and patients written informed consent ,70 patients ASA physical status I or II who are candidates for endoscopic sinus surgery under general anesthesia were recruited in this randomized, double-blind study.After induction of anesthesia with propofol and atracurium and tracheal intubation (the same for all the patients) the patients in two groups received randomly 5 mg/kg or 15 mg/kg intravenous tranexamic acid(souluted in 100 ml of normal saline) as the infusion during 10 minutes . Systolic,diastolic and mean arterial blood pressures and pulse rate are recorded before induction of anesthesia and then 30 , 60 ,90 ,120 ,120 and 180 minutes after that. Also quality of the feild of surgery according to Boezarrt score and satisfaction of the surgeon according to Likertt score are assessed in these times.If the patients need the additional intervention like administration of intravenous TNG to control the intraoperative bleeding ,this is recorded.At the end of the surgery the total amount of blood loss during the surgery and duration of the surgery are reccorded too.Drug side effects (nausea,vomiting ,diarrhea ,abdominal pain and thrombotic complications) evalueded and compared between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203242963N7**
Registration date: **2012-04-06, 1391/01/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-04-06, 1391/01/18

Registrant information

Name

Shekoufeh Behdad

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1822 1386

Email address

drbehdad@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2011-09-13, 1390/06/22

Expected recruitment end date

2012-03-18, 1390/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effects of Two Doses of Intravenous Tranexamic Acid on Blood loss and Feild of the surgery during Endoscopic Sinus Surgery

Public title

Comparison the Effects of Two Doses of Intravenous Tranexamic Acid on Blood loss and Feild of the surgery during Endoscopic Sinus Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA physical status I or II,18-50 aged candidates for endoscopic sinus surgery under general anesthesia Exclusion criteria:Coagulation disorder,history of hypertension,CVA,deep venous thrombosis,coronary artery disease,pulmonary emboli,and peripheral vascular disease.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Sciences

Street address

Bahonar square

City

Yazd

Postal code

Approval date

2011-09-12, 1390/06/21

Ethics committee reference number

71404

Health conditions studied

1

Description of health condition studied

tranexamic acid

ICD-10 code

Y44.5

ICD-10 code description

Thrombolytic drugs

Primary outcomes

1

Description

Amount of blood loss

Timepoint

at the end of the surgery

Method of measurement

The amount of blool in the suction device and the number of blood-soaked gauze

Secondary outcomes

1

Description

Quality of the feild of surgery

Timepoint

At the end of surgery

Method of measurement

Boezarrt score

Intervention groups

1

Description

Intravenous tranexamic acid 5 mg/kg

Category

Treatment - Drugs

2

Description

Intravenous tranexamic acid 15 mg/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

Dr.Shekoufeh Behdad

Street address

Shahid Sadoughi Hospital

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr. Hasan Mozaffari
Street address
Bahonar Square
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadoughi 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
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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