

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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) evaluated 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 blood in the suction device and the number of blood-soaked gauze

## **Secondary outcomes**

### 1

#### **Description**

Quality of the field 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**

**Name of organization / entity**

Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Dr Shekoufeh Behdad

**Position**

Assistant of professor

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Sadoughi Hospital

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*