

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The effect of Tranexamic Acid in decreasing of intraoperative bleeding and need for deliberate hypotension in patients undergoing Functional Endoscopic Sinus Surgery.

#### Protocol summary

##### Summary

The aim of this study is determining the effect of tranexamic acid to reduce intraoperative bleeding in patients undergoing endoscopic sinus surgery. This is a randomized double-blind with a placebo control study . All 16 to 40 years old patients with ASA class 1 in Ahwaz Imam Khomeini hospital that candidate for elective Functional Endoscopic Sinus Surgery are studied. Exclusion criteria were pregnancy and coagulopathy disorders.The sample in this study were calculated 66 patients .Bleeding Calculate by the number of gases and blood soaked into the suction .Patients divided into two groups.Immediately after induction,in case group we infuse 10mg/kg Tranexamic acid in 50cc normal saline in 15 minut and patients in control group recived 50cc normal saline in 15 minut.During the operation the patient's blood pressure is taken every 15 minutes.At the end of surgery all patients reversed and transfered to recovery.In this study we expect decreasing intraoperative bleeding in case group.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012111411455N1**

Registration date: **2013-03-17, 1391/12/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-03-17, 1391/12/27

##### Registrant information

##### Name

Hamidreza Deylamani

##### Name of organization / entity

Ahwaz (Jondishapour) University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1222 0168

##### Email address

deylamani.h@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahwaz (Jondishapour) University of Medical Sciences

##### Expected recruitment start date

2012-05-21, 1391/03/01

##### Expected recruitment end date

2012-12-20, 1391/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Tranexamic Acid in decreasing of intraoperative bleeding and need for deliberate hypotension in patients undergoing Functional Endoscopic Sinus Surgery.

##### Public title

The effect of Tranexamic Acid in decreasing of bleeding in patients undergoing Functional Endoscopic Sinus Surgery.

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria:16\_40 years olds ASA class1 with crhonic sinusitis canditate for surgery. Exclusion

criteria: Pregnancy ; anticoagulant therapy at recent 3 months ; patients with coagulopathy.

### Age

From **16 years** old to **40 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **66**

### 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

Ahvaz (Jondishapour) University of Medical Sciences

##### Street address

Golestan

##### City

Ahvaz

##### Postal code

#### Approval date

2012-06-30, 1391/04/10

#### Ethics committee reference number

Eth-528

## Health conditions studied

### 1

#### Description of health condition studied

Bleeding

#### ICD-10 code

T81.0

#### ICD-10 code description

Haemorrhage and haematoma complicating a procedure, not elsewhere classified

## Primary outcomes

### 1

#### Description

Intraoperative bleeding

#### Timepoint

During the surgery

#### Method of measurement

Number of gases and soaked blood into the suction by milli liter

## Secondary outcomes

### 1

#### Description

Intraoperative blood pressure

#### Timepoint

Every 15 minute

#### Method of measurement

Automated sphygmomanometer by mmhg

## Intervention groups

### 1

#### Description

In intervention group 33 patients 10 mg/kg tranexamic acid in 50 cc normal saline infuse within 15 minute .

#### Category

Treatment - Drugs

### 2

#### Description

In control group 33 patients 50cc normal saline infuse within 15 minute.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Dr Hamidreza Deylmani

##### Street address

Azadegan Avenue

##### City

Ahvaz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz (Jondishapour) University of Medical Sciences

##### Full name of responsible person

Mostafa Fegghi.MD

**Street address**

Golestan

**City**

Ahvaz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz (Jondishapour) 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**

Imam Khomini hospital

**Full name of responsible person**

Hamidreza Deylamani

**Position**

Resident of anesthesiology

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

Azadegan Avenue

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**Postal code****Phone**

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deylamani.h@ajums.ac.ir

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

Imam Khomini Hospital

**Full name of responsible person**

Ali Ghomeishi.MD

**Position**

Assistant Professor of Department of Anesthesiology

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

Imam Khomini Hospital

**Full name of responsible person**

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**Position**

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*