

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of local tranexamic acid plus phenylephrine versus phenylephrine alone on reduction of bleeding and improvement of surgical field during functional endoscopic sinus surgery in patients with chronic rhinosinusitis: a double blinded randomized controlled trial

#### Protocol summary

##### Summary

**Objectives:** To assess the effect of local tranexamic acid on reduction of bleeding and improvement of surgical field during functional endoscopic sinus surgery in patients with chronic rhinosinusitis **Design:** Double blinded randomized controlled trial **Setting and conduct:** The eligible patients with chronic rhinosinusitis who will refer to ENT clinic of Besat hospital in 2013 **Participants** including major eligibility criteria as follows: **Inclusion criteria:** (a) patients with chronic rhinosinusitis with or without polyposis; (b) age of 18 to 60 years; (c) hemoglobin >10 mg/dl; (d) normal CT, BT, INR, PT, PTT. **Exclusion criteria:** (a) having hemorrhagic abnormality such as hemophilia; (b) thrombosis; (c) acute or chronic renal failure; (d) using heparin during 48 hours before surgery; (e) using aspirin during three days before surgery; (f) allergy to tranexamic acid; (g) cirrhosis; (h) chronic diseases such as hypertension, diabetes, and heart failure; (i) pregnancy; (j) color blind; (k) having cardiac stent; (l) having nasal tumor. **Intervention:** 30 patients will receive three pads impregnated with tranexamic acid 5% and phenylephrine 0.5% for 10 minutes in each nasal cavity before surgery. **Control:** 30 patients will receive three pads impregnated only with phenylephrine 0.5% for 10 minutes in each nasal cavity before surgery **Main outcome** including: **Primary outcomes:** (a) quality of surgical field at 15, 30, and 45 minutes after surgery using Boezaart grading with 1-5 scores; (b) bleeding at 15, 30, and 45 minutes after surgery using blood accumulated in the suction chamber after reducing the amount of serum used for washing and measurement of nasopharyngeal pack weight and converting the blood weight into ml. **Secondary outcomes:** measurement of (a) nausea; (b) vomiting; (c) and impaired color vision 24 hours after surgery and three days later.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201212139014N15**

Registration date: **2013-08-11, 1392/05/20**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-08-11, 1392/05/20

##### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences

##### Expected recruitment start date

2013-06-22, 1392/04/01

##### Expected recruitment end date

2013-12-22, 1392/10/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of local tranexamic acid plus phenylephrine versus phenylephrine alone on reduction of bleeding and improvement of surgical field during functional endoscopic sinus surgery in patients with chronic rhinosinusitis: a double blinded randomized controlled trial

**Public title**

Effect of local tranexamic acid plus phenylephrine versus phenylephrine on reduction of bleeding and improvement of surgical field during functional endoscopic sinus surgery in patients with chronic rhinosinusitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: (a) patients with chronic rhinosinusitis with or without polyposis; (b) age of 18 to 60 years; (c) hemoglobin >10 mg/dl; (d) normal CT, BT, INR, PT, PTT. Exclusion criteria: (a) having hemorrhagic abnormality such as hemophilia; (b) thrombosis; (c) acute or chronic renal failure; (d) using heparin during 48 hours before surgery; (e) using aspirin during three days before surgery; (f) allergy to tranexamic acid; (g) cirrhosis; (h) chronic diseases such as hypertension, diabetes, and heart failure; (i) pregnancy; (j) color blind; (k) having cardiac stent; (l) having nasal tumor.

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**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**

Research Ethic Committee of Hamadan University of Medical Sciences

**Street address**

Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Postal code**

6517838695

**Approval date**

2013-04-09, 1392/01/20

**Ethics committee reference number**

D/P/9/35/16

**Health conditions studied****1****Description of health condition studied**

chronic rhinosinusitis

**ICD-10 code**

J32

**ICD-10 code description**

Chronic sinusitis

**Primary outcomes****1****Description**

Quality of surgical field

**Timepoint**

15, 30 and 45 minutes after surgery

**Method of measurement**

using Boezaart grading with 1-5 scores

**2****Description**

Bleeding

**Timepoint**

0.5 and one hour after surgery

**Method of measurement**

using blood accumulated in the suction chamber after reducing the amount of serum used for washing and measurement of nasopharyngeal pack weight and converting the blood weight into ml.

**Secondary outcomes****1****Description**

Nausea

**Timepoint**

24 hours after surgery and three days later

**Method of measurement**

questionnaire

## 2

### Description

Vomiting

### Timepoint

24 hours after surgery and three days later

### Method of measurement

questionnaire

## 3

### Description

Impaired color vision

### Timepoint

24 hours after surgery and three days later

### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

30 patients will receive three pads impregnated with tranexamic acid 5% and phenylephrine 0.5% for 10 minutes in each nasal cavity before surgery

#### Category

Treatment - Drugs

### 2

#### Description

30 patients will receive three pads impregnated only with phenylephrine 0.5% for 10 minutes in each nasal cavity before surgery

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat hospital

##### Full name of responsible person

Dr Javaneh Jahanshahi

##### Street address

Besat Hospital, Imam Hossein Square

##### City

Hamadan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences

#### Full name of responsible person

Dr Heidar Tavilani

#### Street address

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

#### City

Hamadan

#### 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 the Technology, Hamadan  
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

Besat Hospital

##### Full name of responsible person

Dr Sara Pazira

##### Position

Resident of ENT

##### Other areas of specialty/work

##### Street address

Besat Hospital, Imam Hossein Square.

##### City

Hamadan

##### Postal code

##### Phone

00

##### Fax

##### Email

S\_pazira2009@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Besat Hospital

##### Full name of responsible person

Dr Javaneh Jahanshahi

##### Position

Specialist in ENT

##### Other areas of specialty/work

##### Street address

Besat Hospital, Imam Hossein Square

**City**

Hamadan

**Postal code****Phone**

00

**Fax****Email**

J.Jahanshahi@umsha.ac.ir

**Web page address****Person responsible for updating data****Contact****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*