

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of oral tranexamic acid and corticosteroid on blood loss and the quality of the surgical field during endoscopic sinus surgery

#### Protocol summary

##### Summary

The aim of this study is comparing the effect of corticosteroid and tranexamic acid on the bleeding and quality of surgery zone in the nasal sinus endoscopy. This is randomized clinical trial. Inclusion criteria consist of patients with ASA class 1 and 2 with age 15 - 75 year-old and exclusion criteria consist of patients with sensitivity or contraindications to corticosteroid and tranexamic acid. 90 patients were enrolled the study and randomly divided in to 3 groups. In the first group, 1gr oral tranexamic acid was administrated two hours before the surgery and in the second group, 1mgr/kg/day oral prednisolon was administrated for 5 days and the third group will not receive any drug, then the quality of the surgery zone and volume of the bleeding at the end of the surgery will compared between three groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014031016924N1**

Registration date: **2016-06-28, 1395/04/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-06-28, 1395/04/08

##### Registrant information

###### Name

Nasim Valizadeh

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5554 0026

##### Email address

valizadeh-na@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

University of Medical Sciences Kashan, Vice chancellor for research

##### Expected recruitment start date

2013-10-10, 1392/07/18

##### Expected recruitment end date

2014-12-21, 1393/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of oral tranexamic acid and corticosteroid on blood loss and the quality of the surgical field during endoscopic sinus surgery

##### Public title

Comparison of the effect of oral tranexamic acid and corticosteroid on blood loss and the quality of the surgical field during endoscopic sinus surgery

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients with ASA class 1 and 2; aged between 15 to 75 year-old; hemoglobin level more than 10 mg/dl. Exclusion criteria: sensitivity or contraindication of use corticosteroids and tranexamic acid; history of clotting disorders; previous operation at the same region; uncontrolled hypertension; consuming

of corticosteroids in last 2 months .

**Age**

From **15 years** old to **75 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not 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 Kashan University of  
Medical Sciences

**Street address**

Kashan University of Medical sciences, 5 km ghotbeh  
Ravandi Boulevard, Kashan, Isfahan

**City**

Kashan

**Postal code**

87159/81151

**Approval date**

2013-10-09, 1392/07/17

**Ethics committee reference number**

29/5/1/2972/پ

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

chronic sinusitis

**ICD-10 code**

Chronic si

**ICD-10 code description**

J32.0, J32.1

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

Intraoperative blood loss volume

**Timepoint**

At the end of surgery

**Method of measurement**

The amount of the accumulated blood volume in the  
suction and the surgery field

**2****Description**

Quality of the surgery field

**Timepoint**

During surgery

**Method of measurement**

Endoscopy

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

Intraoperative intravenous fluid intake

**Timepoint**

Every 30 minutes during surgery

**Method of measurement**

Administered fluid volume

**Intervention groups****1****Description**

Group 1: Cap 250 mg tranexamic acid 1 gr orally 2 hours  
before surgery

**Category**

Treatment - Drugs

**2****Description**

Group 2: Tab Prednisolone 50 mg with doses 1 mg / kg  
per day orally for 5 days before surgery

**Category**

Treatment - Drugs

**3****Description**

Group 3: will not receive any drug

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Matini Hospital

**Full name of responsible person**

Dr.Mohammad Reza Fazel

**Street address**

Amir Kabir Avenue, Kashan, Isfahan

**City**

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valizadeh-na@kaums.ac.ir

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

Kashan university of medical sciences

**Full name of responsible person**

Mohammad reza Fazel

**Position**

Anesthesiologist

**Other areas of specialty/work****Street address**Kashan University of Medical sciences, 5 km ghotbeh  
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drm fazel@yahoo.com

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice chancellor for research, Kashan University of  
Medical sciences**Full name of responsible person**

Dr.Gholam Ali Hamidi

**Street address**Kashan University of Medical sciences, 5 km ghotbeh  
Ravandi boulevard, Kashan, Isfahan**City**

Kashan

**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, Kashan 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**

Kashan university of medical sciences

**Full name of responsible person**

Nasim Valizadeh

**Position**

Anesthesia resident

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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*