

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Investigation of preoperative oral Tizanidine on blood loss in endoscopic sinus surgery

#### Protocol summary

##### Summary

The aim of this study is to evaluate the effect of Tizanidin on reducing bleeding during endoscopic sinus surgery that is a double blind study on control and test group. The patients are older than 16 years with ASA class I and II, and nasal polyposis that admitted to the Ghaem hospital and without cardiovascular system pathology, hypertension, liver or kidney disease, hemoglobin below 10, have coagulation disorders. Patients were randomly divided into two groups of 25, a control group that receive placebo and the other group will be received 4 mg tizanidine with 50 cc of water, one hour before surgery. After entering patients into the operating room, head up position at 10 degrees, preparation and pre-oxygenation in patients initially for midazolam premedication and Fentanyl injection and then with propofol and Atracurium induction of anesthesia is given. After 5 minutes the patients will be intubated. During surgery vital signs, including blood pressure measurement, ECG, heart rate, pulse oximetry, capnography and BIS are controlled. Systolic and diastolic and mean arterial blood pressure with heart rate are recorded after induction, after intubation, after drug administration and every 5 minutes (half an hour) and then every 10 minutes until the end of the surgery. We evaluate surgeon satisfaction and the amount of bleeding based on the criteria of Boezarrt and Likertt. 3 minutes before the end of surgery anesthetic drugs will be reduced, after the complete return of muscle strength and injection reverse, patients will be extubated and transferred to recovery, and after the acquisition criteria of discharge will be transferred to the ward.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016022625481N2**

Registration date: **2016-10-29, 1395/08/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-10-29, 1395/08/08

##### Registrant information

###### Name

Farzad Hayati

###### Name of organization / entity

Tehran University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3609 4575

###### Email address

fhayati@ut.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research Mashhad University of Medical Sciences

##### Expected recruitment start date

2016-04-03, 1395/01/15

##### Expected recruitment end date

2016-09-22, 1395/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigation of preoperative oral Tizanidine on blood loss in endoscopic sinus surgery

**Public title**

Effects of Tizanidine on sinus endoscopy bleeding

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Age more than 16 years undergoing endoscopic sinus surgery • ASA class I and II Exclusion criteria : • high blood pressure (severe) • liver or kidney disease •coagulopathy • Diabetes • Abnormal blood sugar on the morning of the day of surgery • severe hypotension during surgery that requires intravenous administration of large volumes • Lack of consent to participate in the study have. Aspirin or any anticoagulants drugs. hemoglobin under 10.

**Age**

From **16 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids****1****Registry name**

IR.MUMS.sm.REC.1394.206

**Secondary trial Id**

931463

**Registration date**

1394-06-11, 777/01/-1377

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

**Street address**

Qaem Hospital

**City**

Mashhad

**Postal code****Approval date**

2015-07-22, 1394/04/31

**Ethics committee reference number**

IR.MUMS.sm.REC.1394.206

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

Nasal polyposis

**ICD-10 code****ICD-10 code description****2****Description of health condition studied**

Nasal polyp

**ICD-10 code**

J33.0

**ICD-10 code description**

Polyp of nasal cavity

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

bleeding

**Timepoint**

after 1 hour

**Method of measurement**

check list

**2****Description**

severity of nasal sinus bleeding

**Timepoint**

before induction, after induction, 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80 minutes

**Method of measurement**

heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure

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

surgeon consent

**Timepoint**

based on Likert scale

**Method of measurement**

It will be measured based on a verbal descriptive scale which is related with a visual bleeding score

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

1 intervention groups: In this group of patients receive Placebo with 50 cc of water, one hour before surgery .During surgery patient's vital signs, including blood pressure measurement, ECG, heart rate, pulse oximetry capnography and BIS will be controlled. Systolic and diastolic and mean arterial blood pressure with heart rate are recorded after induction, after intubation, after drug administration and every 5 minutes (half an hour) and then every 10 minutes until the end of the surgery and case are analyzed.Amount of bleeding and surgeon satisfaction will be evaluated based on Boezarrt and Likertt criteria.

**Category**

Treatment - Drugs

**2****Description**

2intervention groups: In this group of patients receive 4mg Tizanidin with 50 cc of water, one hour before surgery .During surgery patient's vital signs, including blood pressure measurement, ECG, heart rate, pulse oximetry Capnography and BIS will be controlled.Systolic and diastolic and mean arterial blood pressure with heart rate are recorded after induction, after intubation, after drug administration and every 5 minutes (half an hour) and then every 10 minutes until the end of the surgery and case are analyzed.Amount of bleeding and surgeon satisfaction will be evaluated based on Boezarrt and Likertt criteria.

**Category**

Treatment - Drugs

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

Ghaem Hospital

**Full name of responsible person**

Saleheh Asghari

**Street address****City**

Mashhad

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Tafaghodi

**Street address**

Vice chancellor for research Mashhad University of Medical Sciences

**City**

Mashhad

**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 of Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Saleheh Asghari

**Position**

Anesthesia resident

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

Ghaem Hospital, Ahmad abad street, Mashhad

**City**

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**Postal code****Phone**

+98 915 516 4334

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fhayati@ut.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Reza Jallaiyan Taghadomi

**Position**

Associate Professor of Mashhad University of Medical Sciences

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

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

saleheh asghari

**Position**

Anesthesia resident

**Other areas of specialty/work**

**Street address**

Mashhad, Ahmad abad Boulevard, Ghaem hospital

**City**

Mashhad

**Postal code**

**Phone**

## 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*