

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

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Email address

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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**

2 intervention 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**

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

Mashhad University of Medical Sciences

Full name of responsible person

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Position

Associate Professor of Mashhad University of Medical Sciences

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Contact

Name of organization / entity

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Full name of responsible person

saleheh asghari

Position

Anesthesia resident

Other areas of specialty/work

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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