

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison the effect of oral Tizanidine and placebo on blood loss and the quality of the surgical field during endoscopic paranasal sinus surgery

Protocol summary

Study aim

The purpose of this study will be to assess the effect of oral Tizanidine premedication on blood loss and the quality of the surgical field during endoscopic paranasal sinus surgery

Design

Clinical trial with two arm parallel groups, randomized trial with double blinded assessment. Study phase will be 2-3.

Settings and conduct

In Urmia Imam Khomeini hospital operating room after induction of anesthesia Amount of bleeding and quality of the surgical field during surgery, mean arterial pressure and postoperative pain will be assessed in recovery and 6 hours after surgery. The anesthesiologist will be unaware which patient will be assigned to which group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 25 to 55 years old; American Society of Anesthesiologists class I; Chronic sinusitis
Exclusion criteria: Patients in whom controlled decreasing blood pressure is contraindicated; Liver and kidney failure; Known sensitivity to tizanidine; Systolic blood pressure above 160 and diastolic blood pressure above 90 mmhg; Heart rate below 50 in minutes; Patients who have received anticoagulant, beta blocker, calcium channel blocker or digoxin

Intervention groups

In the intervention group, patients will receive tizanidine 6 mg and in control group, patients will receive placebo oral, 90 minutes before the operation.

Main outcome variables

Amount of bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160430027677N12**

Registration date: **2019-02-22, 1397/12/03**

Registration timing: **retrospective**

Last update: **2019-02-22, 1397/12/03**

Update count: **0**

Registration date

2019-02-22, 1397/12/03

Registrant information

Name

Shahryar Sane

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 4897

Email address

sane.sh@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-05-20, 1395/02/31

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of oral Tizanidine and placebo on blood loss and the quality of the surgical field during endoscopic paranasal sinus surgery

Public title

The effect of Tizanidine premedication on blood loss and the quality of the surgical field

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Being at the age of 25 to 55 years old ASA (American Society of Anesthesiologists) class I Chronic sinusitis

Exclusion criteria:

Patients in whom controlled decreasing blood pressure is contraindicated Liver and kidney failure Known sensitivity to tizanidine Systolic blood pressure above 160 and diastolic blood pressure above 90 mmhg Heart rate below 50 per minute Patients who have received anticoagulant, beta blocker, calcium channel blocker or digoxin

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into two groups of tizanidine 4mg (group T) and placebo (group P) using Random Allocation Software 2.0, and the target codes will be written on a piece of paper and placed in sealed envelopes with sequential allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug will be administered by the nurse in the ward and at the time of admission, the anesthesiologist will be unaware which patient will be assigned to which group. Drug containers will be identical and only the nurse will know about the contents of each of them, and finally, after collecting information by the resident in training in anesthesiology, the anesthesiology specialist will be informed of the group each patient is assigned to.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Urmia University of Medical Sciences

Street address

Orjanse alley, Resalat blvd

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Urmia

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West Azarbaijan

Postal code

5714783734

Approval date

2016-10-26, 1395/08/05

Ethics committee reference number

IR.UMSU.REC.1395.299

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

bleeding

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Amount of bleeding

Timepoint

during surgery

Method of measurement

Measuring the amount of blood inside the suction device and the gases used

2**Description**

Quality of the surgical field

Timepoint

During surgery

Method of measurement

Boezaart scale

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

pain

Timepoint

At recovery and 6 hours after surgery

Method of measurement

visual analog scale

2

Description

mean arterial pressure

Timepoint

Every 15 minutes during surgery

Method of measurement

Non invasive pressure gauge

Intervention groups

1

Description

Intervention group: patients will receive tizanidine 6 mg oral tablet, 90 minutes before surgery.

Category

Treatment - Drugs

2

Description

Control group: will receive oral placebo 90 minutes before surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Operating room, Khomeini Hospital

Full name of responsible person

Shahryar Sane

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

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research@umsu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

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Latest degree

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