

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of propofol and dexmedetomidine in reducing blood pressure and bleeding during endoscopic sinus surgery

Protocol summary

Summary

Objectives: Endoscopic sinus surgery as the treatment of choice is widely used especially in patients with chronic sinusitis that does not respond to medical therapy. The aim of this study is to compare the effect of propofol with dexmedetomidine in reducing blood pressure and bleeding during endoscopic sinus surgery. Design: Block randomization, double blind, without placebo, trial phase 2, including 100 patients who are candidate for endoscopic sinus surgery. Setting and conduct: Fentanyl, 1 µg/kg, IV injection to induce anesthesia. Nesdonal, 5 mg/kg, IV injection to induce anesthesia. Atracurium, 0.5 mg/kg, IV injection for muscle relaxation. Participants including major eligibility criteria: All patients who are candidate for endoscopic sinus surgery. Intervention: Dexmedetomidine, 1 µg/kg as initial dose and 0.4 to 0.8 µg/kg/h IV infusion. Propofol, 50-150 µg/kg/min IV infusion. Main outcome measures: Bleeding volume, Systolic blood pressure, Diastolic blood pressure, O₂ saturation, Heart rate.

Country

Iran (Islamic Republic of)

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Email address

he_modir@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101814056N5**

Registration date: **2016-01-09, 1394/10/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-09, 1394/10/19

Registrant information

Name

Hesameddin Modir

Name of organization / entity

Scientific title

Comparison of propofol and dexmedetomidine in reducing blood pressure and bleeding during endoscopic sinus surgery

Public title

Comparison of two medications in reducing blood pressure and bleeding in sinus surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ASA class I-II; Age between 18-60 years old; Patients satisfaction; Not pregnant; No history of cardiovascular diseases (Arrhythmia, ischemia, and heart block); Not history of coagulopathies; Not taking opioids. Exclusion criteria: Sensitivity to the drugs used in this study.

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: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study the randomization was conducted using a random numbers table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

City

Arak

Postal code

Approval date

2015-11-22, 1394/09/01

Ethics committee reference number

IR.ARAKMU.REC.1394.228

Health conditions studied

1

Description of health condition studied

Chronic sinusitis

ICD-10 code

J32

ICD-10 code description

Chronic sinusitis

Primary outcomes

1

Description

Mean arterial pressure

Timepoint

Every 15 minutes to the end of surgery

Method of measurement

Sphygmometer

2

Description

Bleeding volume

Timepoint

During surgery

Method of measurement

The number of gas consumed and the amount of blood suctioned

Secondary outcomes

empty

Intervention groups

1

Description

Dexmedetomidine, 1 µg/kg as initial dose and 0.4 to 0.8 µg/kg/h IV infusion. Propofol, 50-150 µg/kg/min IV infusion.

Category

Prevention

2

Description

Propofol, 50-150 µg/kg/min IV infusion.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir kabir hospital

Full name of responsible person

Dr Hesameddin Modir

Street address

Amir kabir hospital. Parastar square. Rah-Ahan street. Arak. Iran

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences, Vice Chancellor
for Research

Full name of responsible person

Dr Ali Asghar Yaghoobi

Street address

Arak University of Medical Sciences. Basij Square.
Sardasht. Arak. Iran

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak University of Medical Sciences, Vice Chancellor for
Research

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

Arak University of Medical Sciences

Full name of responsible person

Dr Hesameddin Modir

Position

Anesthesiologist

Other areas of specialty/work

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Person responsible for updating data

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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