

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of labetalol and dexmedetomidine on 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 labetalol 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 and propofol, 2.5 mg/kg IV administer to induce anesthesia. 0.5 mg/kg Atracurium IV infusion for muscle relaxation. Major inclusion criteria: ASA class I to II; Age between 18 to 60 years old; Patients satisfaction. Exclusion criteria: pregnancy; history of cardiovascular diseases (Arrhythmia, ischemia, and heart block); history of coagulopathies; taking opioids; History of sensitivity to the drugs used in this study. Intervention: Dexmedetomidine, 1 µg/kg as initial dose and 0.4 to 0.8 µg/kg/h IV infusion. labetalol 0.25 mg/kg as initial dose and 1 to 2 mg/min IV infusion. Main outcome measures: Bleeding volume, Systolic blood pressure, Diastolic blood pressure, O2 saturation, Heart rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080914056N8**

Registration date: **2016-09-15, 1395/06/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-15, 1395/06/25

Registrant information

Name

Hesameddin Modir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3313 9680

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

2016-01-18, 1394/10/28

Expected recruitment end date

2017-01-17, 1395/10/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of labetalol and dexmedetomidine on reducing blood pressure and bleeding during endoscopic sinus surgery

Public title

Comparison of labetalol and dexmedetomidin on bleeding during endoscopic sinus surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ASA class I and II; Age between 18 to 60 years old; Patients satisfaction. Exclusion criteria: pregnancy; history of cardiovascular diseases (Arrhythmia, ischemia, and heart block); history of

coagulopathies; taking opioids; History of 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)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study the randomization was conducted with block randomization method

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

2016-01-18, 1394/10/28

Ethics committee reference number

IR.ARAKMU.REC.1394.288

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

Bleeding volume

Timepoint

End of surgery

Method of measurement

Suctioned blood volume

2

Description

Mean arterial pressure

Timepoint

Every 10 minutes till the end of surgery

Method of measurement

In mmHg with intra arterial manometry

3

Description

O2 saturation

Timepoint

Every 10 minutes till the end of surgery

Method of measurement

Pulse oxymeter

4

Description

heart rate

Timepoint

Every 10 minutes till the end of surgery

Method of measurement

With cardiac monitoring

Secondary outcomes

empty

Intervention groups

1

Description

Dexmedetomidine at dose of 1 µg/kg injected over 10 minutes then 0.4 to 0.8 µg/kg/h IV infused.

Category

Prevention

2

Description

Labetalol at dose of 0.25 mg/kg injected over 10 minutes then 1 to1 mg/min IV infused.

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 Mohammad Rafeie

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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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