

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 to 1 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****Street address**

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

**City**

Arak

**Postal code****Phone**

+98 86 3417 3641

**Fax****Email**

He\_modir@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Hesameddin Modir

**Position**

Anesthesiologist

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

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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*