# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 May 2026

## The effect of oral clonidine and intravenous dexmedetomidine administration on bleeding during functional endoscopic sinus surgery

## Protocol summary

**Study aim**
The purpose of this study will be to assess the effect of oral clonidine and intravenous dexmedetomidine administration on bleeding during functional endoscopic 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, mean arterial pressure and heart rate during surgery will be to assess.The anesthesiologist will be unaware which patient will be assigned to which group.

**Participants/Inclusion and exclusion criteria**
Patients with diabetes mellitus, Coagulation problems, Liver or kidney failure, Cerebrovascular disease, High blood pressure, Asthma, Chronic obstructive, pulmonary disease, Severe end organ damage, Psychosis, Patients receiving antipsychotic medication, Hypersensitivity to dexmedetomidine and clonidine, Drug abusers, Use of beta blockers drugs, Heart rate less than 55 beats per minute

**Intervention groups**
In first intervention group: patients will receive Clonidine 200 mcg oral tablet, 90 minutes before surgery. In second Intervention group patients in Group dexmedetomidine will be received 0.4 mcg/kg/h during surgery. In control group patients will be received oral placebo 90 minutes before surgery and saline Infusion during surgery.

**Main outcome variables**
Amount of bleeding

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20160430027677N20**
Registration date: **2020-11-02, 1399/08/12**
Registration timing: **retrospective**

Last update: **2020-11-02, 1399/08/12**
Update count: **0**

**Registration date**
2020-11-02, 1399/08/12

**Registrant information**

**Name**
Shahryar Sane

**Name of organization / entity**
Urmia University of Medical Sciences

**Country**
Iran (Islamic Republic of)

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+98 44 3223 4897

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-05-22, 1398/03/01

**Expected recruitment end date**
2019-12-22, 1398/10/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effect of oral clonidine and intravenous dexmedetomidine administration on bleeding during

functional endoscopic sinus surgery

**Public title**
Evaluation the effect of clonidine and dexmedetomidine administration on bleeding during surgery
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Aged 20-60 years old American Society of Anesthesiologists physical status classification I,II General anesthesia
**Exclusion criteria:**
Patients with diabetes mellitus Coagulation problems Liver or kidney failure Cerebrovascular disease High blood pressure Asthma Chronic obstructive pulmonary disease Severe end organ damage Psychosis Patients receiving antipsychotic medication Hypersensitivity to dexmedetomidine and clonidine Drug abusers Use of beta blockers drugs Heart rate less than 55 beats per minute
**Age**
From **20 years** old to **60 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**

- Investigator
- Outcome assessor

**Sample size**
Target sample size: **64**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patients will be randomly assigned into three groups of Dexmedetomidine (group D)and Clonidine (group C) and placebo (group P) using Random Allocation Software 2.0, and the target codes will be written and placed in sealed envelopes with sequential allocation using double-blind method.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
The anesthesiologist will be unaware of which patient will be assigned to which group. Oral clonidine drug and dexmedetomidine syringes will be identical and only the operating room and ward nurse will knew about the contents of each of them, and finally, after collecting information from the anesthesia residents, the anesthesiologist will be informed of the group each patient will be assigned to.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics commitee of Urmia University of Medical Sciences
**Street address**
Emergent Street, Ershad Avenue
**City**
Urmia
**Province**
West Azarbaijan
**Postal code**
5714783734
**Approval date**
2019-05-15, 1398/02/25
**Ethics committee reference number**
IR.UMSU.REC.1398.079

## 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**
mean arterial pressure
**Timepoint**
Every 5 minutes during the surgery
**Method of measurement**
Non invasive pressure gauge

**2**

**Description**
Mean pulse Rate
**Timepoint**
Every 5 minutes during the surgery
**Method of measurement**
Electrocardiogram

## Intervention groups

**1**

**Description**
Intervention group: patients will receive Clonidine 200 mcg oral tablet, 90 minutes before surgery.
**Category**
Prevention

**2**

**Description**
Intervention group: Patients in Group dexmedetomidine will be received 0.4 mcg/kg/h
**Category**
Prevention

**3**

**Description**
Control group: will be received oral placebo 90 minutes before surgery and saline Infusion during 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**
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Oroumia University of Medical Sciences
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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?**
No
**Title of funding source**
Umia 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
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Anesthesiology
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## Person responsible for updating data

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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