Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)
Phone
+98 44 3223 4897
Email address
sane.sh@umsu.ac.ir

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
Street address
Ershad blvd, Modarres blvd
City
Urmia
Province
West Azarbaijan
Postal code
5715781351
Phone
+98 44 3346 9931
Fax
+98 44 3346 8967
Email
emam-h-urm@umsu.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Iraj Mohebbi
Street address
Orjanse alley, Resalat blvd
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Fax
+98 44 3223 4897
Email
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
Other areas of specialty/work
Anesthesiology
Street address
Orjanse alley, Resalat blvd
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897

Fax
+98 44 3346 8967
Email
sanesh@umsu.ac.ir
Web page address

Person responsible for scientific 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
Street address
Orjanse alley, Resalat blvd
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Fax
+98 44 3346 8967
Email
sanesh@umsu.ac.ir

Person responsible for updating data

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
Street address
Orjanse alley, Resalat blvd
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Fax
+98 44 3346 8967
Email
sanesh@umsu.ac.ir

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