Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Sep 2026

Assesment of topical dexmedetomidine administration on intraoperative bleeding and quality of the surgical field during functional endoscopic sinus surgery in patients with chronic rhinosinusitis

Protocol summary

Study aim

Assesment of topical dexmedetomidine administration on intraoperative bleeding and quality of the surgical field during functional endoscopic sinus surgery

Design

a randomized, triple blinded, controlled clinical trial with 44 patients with chronic rhinosinusitis candidate for functional endoscopic sinus surgery enrolled between september 2018 and September 2019

Settings and conduct

dexmedetomidine 2MCG/kg (in 2 ml with normal saline) will be coded by a technician who will not involve in other stages of study and 20 minutes before beginning of surgery will drop in each nostril. Quality of the field of surgery will evaluated at minutes 15,30,60 and 90.Also the amount of bleeding will be estimated from content of suction bottle.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Patients with chronic rhinosinusitis with or without polyposis candidate for FESS -18 - 60 years old -lack of history of bleeding disorders such as hemophilia - Normal coagulation tests - exclusion Criteria: - history of thromboembolic events - history of acute or chronic renal failure - use of anti-coagulant drugs since 5 days before surgery -history of cirrhosis- systemic diseases such as hypertension, diabetes, heart failure and cardiac rhythm disorders and coronary disorder- pregnancy - Allergy to dexmedetomidine - Sinonasal neoplasm -Detection of omplications during surgery or anesthesia

Intervention groups

In all patients 20 minutes before the operation, nasal solution dexmedetomidine or saline will be used in each nasal side (1ml In each nostril).

Main outcome variables

Quality of the field of surgery and the amount of bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100126003186N12**
Registration date: **2019-09-24, 1398/07/02**
Registration timing: **retrospective**

Last update: **2019-09-24, 1398/07/02**
Update count: **0**

Registration date

2019-09-24, 1398/07/02

Registrant information

Name

Farnaz Hashemian

Name of organization / entity

Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assesment of topical dexmedetomidine administration on intraoperative bleeding and quality of the surgical field during functional endoscopic sinus surgery in patients with chronic rhinosinusitis

Public title

Assesment of topical dexmedetomidine administration on intraoperative bleeding during functional endoscopic sinus surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic rhinosinusitis with or without polyposis candidate for FESS surgery Age between 18 and 60 years Lack of history of bleeding disorders such as hemophilia and ... and the disruptions of coagulation tests (PT, PTT, INR, BT, CT and platelet counts)

Exclusion criteria:

Allergy to dexmedetomidine Detection of complications during surgery or anesthesia requiring special action Patients with sinonasal tumors history of thromboembolic events history of acute or chronic renal failure take of anti-coagulant drugs for up to five days before surgery hepatic cirrhosis systemic diseases such as hypertension, diabetes, heart failure, cardiac rhythm disorders, and coronary artery disease pregnancy

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose, the block randomization method will be used. Hence, six sheets will be prepared (letter A will be written on three sheets and letter B on the other three sheets for the Intervention and Control group). The sheets will be mixed together and placed in the drawer of the table. By referring to each of the eligible patients, one of the sheets will drawn randomly and based on the sheet A or B the patient will be allocated into one of the two intervention and control groups. The drawn sheets will not be returned to the drawer until all six sheets will be drowned.

Blinding (investigator's opinion)

Triple blinded

Blinding description

For both intervention and control groups, syringes with unspecified content (saline or dexmedetomidine) are used twenty minutes before surgery. The saline solution is drawn in a syringe similar to the dexmedetomidine solution (syringes will be prepared and identified with codes A and B by an operating room technician who will not participate in the course of the research project. So the codes will remain hidden till the end of the study and analysis). Therefore, the study will be blinded for the patients, the surgeon and the data analyser.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamedan University of Medical Sciences

Street address

Hamadan university of medical sciences, Shahid Fahmideh Ave., Hamadan,

City

Hamadan

Province

Hamadan

Postal code

6514845411

Approval date

2018-05-10, 1397/02/20

Ethics committee reference number

IR.UMSHA.REC.1397.220

Health conditions studied

1

Description of health condition studied

Chronic rhinosinusitis

ICD-10 code

J32.4

ICD-10 code description

Chronic pansinusitis

Primary outcomes

1

Description

Quality of surgical field

Timepoint

15th, 30th, 60th and 90th minutes after surgery

Method of measurement

The quality of vision of surgical field was measured

based on Boezaart Grading.

2

Description
amount of bleeding during surgery
Timepoint
15th, 30th, 60th and 90th minutes after surgery
Method of measurement
the amount of intraoperative bleeding, based on the amount of blood collected in the bottle of suction will be estimated.

Secondary outcomes

1

Description
The amount of pain
Timepoint
12 and 24 hours after surgery
Method of measurement
Visual Analogue Scale

2

Description
Median arterial pressure
Timepoint
15th, 30th, 60th and 90th minutes after surgery
Method of measurement
using automated sphygmomanometer

Intervention groups

1

Description
Intervention group: 2 microgram / kg dexmedetomidine which reached to 2 Ml with normal saline will be instilled into both nostrils, twenty minutes before surgery.(1 Ml to each nostril)
Category
Treatment - Surgery

2

Description
Control group: 2 Ml normal saline will be instilled into both nostrils, twenty minutes before surgery.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat hospital, Hamedan, Otolaryngology clinic
Full name of responsible person
Dr farnaz hashemian
Street address
ENT clinic, Besat hospital, Shahid motahari Blvd, Hamedan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Hamedan University of Medical Sciences
Full name of responsible person
Dr farnaz Hashemian

Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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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