

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Efficacy of Dexmedetomidine infusion on the bleeding and quality of surgical field in patients who undergo endoscopic sinus surgery

Protocol summary

Summary

This is a randomized double-blind clinical trial (in terms of the patients, surgeon and researcher) which investigates the efficacy of Dexmedetomidine on the surgical bleeding and field in 72 patients who undergo endoscopic sinus surgery at Amiralmomenin Hospital_Rasht. After explaining the process of the trial, written informed consent obtained from participants, they will be divided into two groups as random fixed block (36 patients in each group). Patients are excluded with use of anticoagulants; history of Acute and chronic renal failure; Diabetes; stroke; Coronary artery disease; hypertension; Deep vein thrombosis; Pulmonary embolism; peripheral vascular diseases; pregnancy. First group will receive Dexmedetomidine 1 /mg/kg in 10 mL of saline 0.9% dilution during the 10 minutes before induction of anaesthesia and then infusion continues at a dose of 0.2 to 1/mg/kg/hr and the second group receive only anaesthesia similar to the first group without infusion of Dexmedetomidine. For all patients anesthetic protocol are the same. The collected information will include: volume of bleeding during surgery on the scale Boezaart and systolic and diastolic blood pressure and Mean Arterial Pressure and heart rate in the time intervals between 15, 30, 60 and 90 minutes, and the surgeon satisfaction based on Likert scale (1-very bad to 5- very good), surgical time and complications of Dexmedetomidine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606211138N23**

Registration date: **2016-08-13, 1395/05/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-13, 1395/05/23

Registrant information

Name

Fataneh Bakhshi

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Science, Vice Chancellor for Research

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Dexmedetomidine infusion on the bleeding and quality of surgical field in patients who undergo endoscopic sinus surgery

Public title

Efficacy of Dexmedetomidine infusion on the bleeding in endoscopic sinus surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged between 16-60 years who undergo endoscopic sinus surgery; those with hemoglobin more than 10 mg/dL; normal clotting time and bleeding time; normal PT; PTT; INR; no history of airways problems and systemic disease or Mental disorders; no history of the anesthetic drugs sensitivity or any other medication and no history of bleeding disorders (such as hemophilia) ;Exclusion criteria: Use of anticoagulants such as heparin 48 hours before surgery; history of acute and chronic renal failure; diabetes; stroke; coronary artery disease; hypertension; deep vein thrombosis; pulmonary embolism; peripheral vascular diseases; pregnancy.

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Science

Street address

Vice-Chancellor for Research Building, Opposite of Sepah Bank, Shahid Beheshti Blvd, Rasht

City

Rasht

Postal code

Approval date

2016-06-14, 1395/03/25

Ethics committee reference number

IR.GUMS.REC.1395.75

Health conditions studied

1

Description of health condition studied

Chronic sinusitis

ICD-10 code

J32.9

ICD-10 code description

Chronic sinusitis

Primary outcomes

1

Description

The amount of bleeding during surgery

Timepoint

in time intervals between 15; 30; 60 and 90 minutes

Method of measurement

scale Boezaart

Secondary outcomes

1

Description

systolic and diastolic blood pressure and Mean Arterial Pressure

Timepoint

in time intervals between 15; 30; 60 and 90 minutes

Method of measurement

Mercury manometers

2

Description

heart rate

Timepoint

in time intervals between 15; 30; 60 and 90 minutes

Method of measurement

Electrocardiogram

3

Description

surgeon satisfaction

Timepoint

in time intervals between 15; 30; 60 and 90 minutes

Method of measurement

Likert scale

4

Description

Duration of surgery

Timepoint

in time intervals between 15; 30; 60 and 90 minutes

Method of measurement

clock

Intervention groups

1

Description

First group: Dexmedetomidine 1/mg /kg in 10 mL of saline 9/0% during the 10 minutes before induction of anesthesia and then infusion continues at a dose of 0.2 to 1/mg/kg/hr.

Category

Prevention

2

Description

second group: receive only anesthesia similar to the first group without infusion of Dexmedetomidine.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Dr Sudابه Haddadi

Street address

Amiralmomenin Hospital, 17 Shahrivar St

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Science, Vice Chancellor for Research

Full name of responsible person

Susan Komae

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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

Guilan University of Medical Science, 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

Guilan University of Medical Sciences

Full name of responsible person

Dr Soudابه Haddadi

Position

Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

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