

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of dexmedetomidine infusion in control bleeding and postoperative pain in functional endoscopic sinus surgery

Protocol summary

Summary

The aim of this double-blind clinical trial study was to evaluate the effect of intravenous infusion of Dexmedetomidin to control bleeding and postoperative pain in functional endoscopic sinus surgery in Matini, Kashan Hospital. Inclusion criteria included patients aged between 15 and 75 years of age, ASA class I, II, and HB>10grdlin patient whit Pansinusitis. Exclusion criteria included history of sensitivity to Dexmedetomidin, coagulation disorders, past surgical history at the same of location, uncontrolled high blood pressure. Samples were randomly divided into 3 groups of 32 individuals in intervention and control groups. Group A infusion Dexmedetomidin 0.2 µ/ Kg/h and Group B infusion Dexmedetomidin 0.5 µ/Kg/h, Group C infusion Normal saline with the volume equal to a dose of Dexmedetomidine. Induction was carried out by using 0.03 mg Midazolam, 2 µ/ kg Fentanyl, 2mg/kg Propofol, 0.5 mg/kg Atracurium. For maintenance purposes, 50% N20-O2 was combined with 100µ/kg/min Propofol. The bleeding rate was also examined and recorded based on the weight of gases and volume of the suction tank. In wake-up time from reverse injection until eyes opening, Patents were recovered from anesthesia whit using 0.06 mg/kg Neostigmine and 0.03 mg/kg Atropin .Main outcome measures: Bleeding volume, Systolic blood pressure, Diastolic blood pressure, O2 saturation, Heart rate, postoperative pain in recovery and in 2, 6, 12, 24 hour after surgery in the ward.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082935987N1**

Registration date: **2017-10-24, 1396/08/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-24, 1396/08/02

Registrant information

Name

Fahimeh Abam

Name of organization / entity

Kashan University of Medical Sciences

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Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of dexmedetomidine infusion in control bleeding and postoperative pain in functional endoscopic sinus surgery

Public title

Effect of dexmedetomidine infusion in control bleeding and postoperative pain in functional endoscopic sinus

surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged between 15 and 75 years of age, ASA class I, II, and HB>10g/dl in patient with Pansinusitis. Exclusion criteria: history of sensitivity to Dexmedetomidine, coagulation disorders, past surgical history at the same of location, uncontrolled high blood pressure

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Ghotbe Ravand Boulevard, Kashan

City

Kashan

Postal code

Approval date

2016-12-08, 1395/09/18

Ethics committee reference number

IR.KAUMS.REC.1395.102

Health conditions studied

1

Description of health condition studied

Chronic pansinusitis

ICD-10 code

J32.4

ICD-10 code description

Pansinusitis NOS

Primary outcomes

1

Description

Bleeding volume

Timepoint

During surgery

Method of measurement

The number of gas consumed and the amount of blood suctioned

2

Description

Mean arterial pressure

Timepoint

Every 15 minutes till the end of surgery

Method of measurement

In mmHg with intra arterial manometry

3

Description

heart rate

Timepoint

Every 15 minutes till the end of surgery

Method of measurement

With cardiac monitoring

4

Description

Pain severity

Timepoint

In recovery, after 2,6,12,24 hour in ward

Method of measurement

visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Group1: Infusion Dexmedetomidin 0.2 µ/ Kg/h

Category

Prevention

2

Description

Group 2: Infusion Dexmedetomidin 0.5 µ /Kg/h

Category

Prevention

3

Description

Group 3: Infusion Normal saline with the volume equal to a dose of Dexmedetomidin

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Matini Hospital

Full name of responsible person

Street address

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholam Ali Hamidi

Street address

Ghotbe Ravandi Boulevard, Kashan

City

kashan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Kashan University of Medical Sciences

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

Kashan University of Medical Sciences

Full name of responsible person

Fahimeh Absm

Position

Assistant Anesthesiologist

Other areas of specialty/work

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Fahimeh Abam

Position

Assistant Anesthesiologist

Other areas of specialty/work

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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