# 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 andin2, 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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**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>10grdlin patient whit 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: Iinfusion 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**
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## Person responsible for updating data

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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*