# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Effect of intravenous infusion of dexmedetomidine in control bleeding during functional endoscopic sinus surgery

## Protocol summary

**Summary**

The aim of this double-blind clinical trial study was to evaluate the intravenous infusion effect of dexmedetomidine to control bleeding during functional endoscopic sinus surgery in 2016 in Imam Khomeini Hospital, Ahwaz. Inclusion criteria included patients aged between 18 and 60 years of age, ASA class I, II and exclusion criteria included diabetes mellitus, coagulation disorders, kidney and liver dysfunction, cerebrovascular disease, cardiovascular disease, high blood pressure, asthma, COPD, psychiatric disease, drug allergy, taking beta-blockers, heart rate less than 55. Samples were randomly divided into two groups of 30 individuals in intervention and control groups. Induction was carried out by using 1 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, 0.2 µ/kg/min remifentanil. 1µ/kg dexmedetomidine was injected within 10 minutes in the intervention group then 0.5 µ/kg/hr of dexmedetomidine infusion began. Also, normal saline was used in the control group with the volume equal to a dose of dexmedetomidine. Then the blood pressure and heart rate were measured every 5 minutes up to the reversal of neuromasular blockade. The bleeding rate was also examined and recorded based on the weight of gases and volume of the suction tank, wake-up time from reverse injection until eyes opening, intraoperative drug consumption and the severity of nausea and vomiting within two hours of recovery. Dexmedetomidine as well as propofol and remifentanil infusion was discontinued respectively 15 and 5 minutes before the end of surgery. Patents were recovered from anesthesia using 0.05 mg/kg neostigmine and 0.02 mg/kg atropine.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017012929256N2**
Registration date: **2017-03-04, 1395/12/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2017-03-04, 1395/12/14

**Registrant information**

**Name**
Shahrzad Pooyan

**Name of organization / entity**
Ahvaz Jodishapur University

**Country**
Iran (Islamic Republic of)

**Phone**
+98 71 3822 1266

**Email address**
pooyan.sh@ajums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

vice-chancellor for research and technology of Ahvaz Jundishapur University of Medical Sciences

**Expected recruitment start date**

2016-04-03, 1395/01/15

**Expected recruitment end date**

2016-10-22, 1395/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of intravenous infusion of dexmedetomidine in control bleeding during functional endoscopic sinus

surgery

**Public title**
Effect of of dexmedetomidine in control bleeding during sinus surgery
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
Inclusion criteria: Patients undergoing endoscopic sinus surgery; aged between 16 and 60 years; ASA class I and II. Exclusion Criteria: diabetes mellitus; coagulation disorders; kidney and liver dysfunction; cerebrovascular disease; cardiovascular disease; high blood pressure; asthma; chronic obstructive pulmonary disease; psychiatric patients; drug allergy; taking beta-blockers; heart rate of less than 55.
**Age**
From **16 years** old to **60 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**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**
Ahvaz Jundishapur University of Medical Sciences Ethics Committee
**Street address**
Ethics Committee, Vice-Chancellor for Research and Technology, Ahvaz University of Medical Sciences, Golestan street, Ahvaz
**City**
Ahvaz
**Postal code**
**Approval date**
2016-11-26, 1395/09/06
**Ethics committee reference number**
IR.AJUMS.REC.1395.558

## Health conditions studied

**1**

**Description of health condition studied**
Haemorrhagic condition
**ICD-10 code**
D69.9
**ICD-10 code description**
Haemorrhagic condition, unspecified

## Primary outcomes

**1**

**Description**
bleeding
**Timepoint**
q 15 minute up to the end of anesthesia
**Method of measurement**
data collected from standard operting room monitoring systems

## Secondary outcomes

**1**

**Description**
nausea and vomit
**Timepoint**
every 30 minutes during 2 hours recovery time
**Method of measurement**
VAS score

**2**

**Description**
awakening time
**Timepoint**
after injection of neuromascular blockade
**Method of measurement**
time after reversal of neuromasculare blockade till eye opening on command

## Intervention groups

**1**

**Description**
Intervention group: After induction of anesthesia 1µ/kg/min Dexmedtomidin be injected within 10 minutes, then dexmedtomidin infusion begins with 0.5 µ /kg/minute.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: After induction of anesthesia, 50 ml normal saline as placebo administrated.
**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Imam khomeini Hospital of Ahvaz

**Full name of responsible person**
Sharzad pouyan

**Street address**
Imam khomeini hospital of ahvaz, azadegan Street, Ahvaz, khozestan.

**City**
Ahvaz

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Vice-Chancellor for Research and Technology of Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**
Dr Makhmalzadeh

**Street address**
Ahvaz Jundishapur University of Medical Sciences, vice-chancellor for research and technology, Golestan street, Ahvaz, Khozestan

**City**
Ahvaz

**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 and Technology of Ahvaz Jundishapur 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**
Ahvaz Jundishapor University of Medical Sciences

**Full name of responsible person**
Sharzad Pooyan

**Position**
Anesthesia resident

**Other areas of specialty/work**

**Street address**
Ahvaz Jundishapur University of Medical Sciences, medicine school, Golestan road, Ahvaz, Khozestan

**City**
Ahvaz

**Postal code**

**Phone**
+98 61 3571 5794

**Fax**

**Email**
sheripooya@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Ahvaz Jundishapor University of Medical Sciences

**Full name of responsible person**
Sharzad Pooyan

**Position**
Anesthesia resident

**Other areas of specialty/work**

**Street address**
Ahvaz Jundishapur University of Medical Sciences, medicine school, Golestan road, Ahvaz, Khozestan

**City**
Ahvaz

**Postal code**

**Phone**
+98 61 3571 5794

**Fax**

**Email**
sheripooya@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Ahvaz Jundishapor University of Medical Sciences

**Full name of responsible person**
Sharzad Pooyan

**Position**
Anesthesia resident

**Other areas of specialty/work**

**Street address**
Ahvaz Jundishapur University of Medical Sciences, medicine school, Golestan road, Ahvaz, Khozestan

**City**
Ahvaz

**Postal code**

**Phone**
00

**Fax**

**Email**

**Web page address**

## 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*