

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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% N2O-O2 was combined with 100µ/kg/min propofol, 0.2 µ/kg/min remifentanyl. 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 neuromuscular 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 remifentanyl infusion was discontinued respectively 15 and 5 minutes before the end of surgery. Patients 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

Ahwaz 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 Ahwaz 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 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 operating 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 neuromuscular blockade

Method of measurement

time after reversal of neuromuscular blockade till eye
opening on command

Intervention groups

1

Description

Intervention group: After induction of anesthesia 1 μ /kg/min Dexmedetomidin be injected within 10 minutes, then dexmedetomidin 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

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 Jundishapur 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,
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City

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Other areas of specialty/work**Street address**

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Person responsible for updating data

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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