Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison between clonidine and Dexmedetomidine as premedication on hemodynamic changes and intraoperative bleeding in spine surgery

Protocol summary

Summary

This randomized, double-blind clinical trial study, was performed during 2014-15 on 120 patients undergoing spine surgery. Inclusion criteria were as follows: age range of 20 to 50 years, ASA class 1 or 2 and spine surgery candidates. Exclusion criteria included patients with hypertension, diabetes, clotting problems, ischemic heart disease, drug or alcohol abuse, pregnancy, taking beta blockers or calcium channels blockers drugs and operating time of over 120 minutes. Patients were randomly divided into three groups. The first group took an oral clonidine 0.2 mg tablet 30 minutes before entering the room and 100cc saline as placebo 15 minutes before induction of anesthesia. The second group received placebo pills and 0.5 µ/kg dexmedetomidine 15 minutes before induction of anesthesia in 100cc saline infusion with continuation rate of 0.25µ/h. The third group received placebo tablets plus 100cc saline infusion taken 15 minutes before induction of anesthesia. All three groups underwent general anesthesia with fentanyl 3.0 µg/kg, thiopental 3-5 mg/kg, atracurium 0.5 mg/kg. Maintenance of anesthesia was done with 0.5-1% isoflurane, 50% N2O and 50% O2. During surgery the anesthesiologist, by calculating the amount of required fluid, administrated the sufficient volume of crystalloid to the patients. Heart rate, systolic blood pressure and diastolic arterial pressure before induction of anesthesia were registered as a baseline using the designated arterial line one minute after intubation and subsequently 10, 20, 30 minutes after induction of anesthesia and after extubation. The amount of intraoperative blood loss of each patient was estimated based on the volume of blood in the suction bottle and the number of the bloody gauze pads.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011225982N1**
Registration date: **2016-01-25, 1394/11/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-01-25, 1394/11/05

Registrant information

Name

Mahshid Vaziri

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 914 452 4964

Email address

vaziri.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Assistant of Research and Technology Development-Ahvaz-Dr Nader Saki

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between clonidine and Dexmedetomidine as premedication on hemodynamic changes and

intraoperative bleeding in spine surgery

Public title
Comparison between clonidine and Dexmedetomidine as premedication on hemodynamic changes and intraoperative bleeding
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria were as follows: age range of 20 to 50 years, ASA class 1 or 2 and spine surgery candidates. Exclusion criteria included patients with hypertension, diabetes, clotting problems, ischemic heart disease, drug or alcohol abuse, pregnancy, taking beta blockers or calcium channels blockers drugs and operating time of over 120 minutes.
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
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
Street address
Golestan Blvd., Ahvaz, Khuzestan Ahvaz University of Medical Sciences Ethics Committee
City
Ahvaz
Postal code
Approval date
2015-11-21, 1394/08/30
Ethics committee reference number
ajums.erc.1394.454

Health conditions studied

1

Description of health condition studied
Bleeding
ICD-10 code
T81
ICD-10 code description
Complications of procedures, not elsewhere classified

2

Description of health condition studied
Hemodynamic Changes
ICD-10 code
R00.0, R00
ICD-10 code description
Tachycardia (unspecified), Bradycardia (unspecified), Palpitations

Primary outcomes

1

Description
Intraoperative bleeding
Timepoint
Ending surgery
Method of measurement
Including suction bottle and blood gauzes

Secondary outcomes

1

Description
Heart Rate
Timepoint
One minute after intubation, 10, 20, 30 minutes after induction of anesthesia and after extubation
Method of measurement
ECG Monitoring

2

Description
Blood Pressure
Timepoint
One minute after intubation, 10, 20, 30 minutes after induction of anesthesia and after extubation
Method of measurement
Invasive blood pressure monitoring

3

Description
Mean Arterial Pressure
Timepoint
One minute after intubation, 10, 20, 30 minutes after induction of anesthesia and after extubation
Method of measurement

Invasive blood pressure monitoring

Intervention groups

1

Description
The first group intervention: clonidine 0.2 mg tablets 45 minutes before induction of anesthesia and saline infusion as a placebo to 100 ml 15 minutes before induction of anesthesia
Category
Treatment - Other

2

Description
The second group intervention: placebo tablets and infusion Dexmedetomidine 0.5 micrograms per kg in 100 mL normal saline 15 minutes before induction of anesthesia to continue the infusion of 0.25 mg per kg per hour, pump the syringe 20 mL with a concentration of 5 mg/ cc
Category
Treatment - Other

3

Description
Control group: placebo tablets with 100 mL of normal saline infusion took 15 minutes before induction of anesthesia
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
Dr Mahshid Vaziri
Street address
Golestan Blvd., Ahvaz Golestan hospital-Genera operating rooml
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr Nader Saki
Street address
Assistant of Research and Technology Development-Ahvaz
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Mahshid Vaziri
Position
Resident of Anesthesiology
Other areas of specialty/work
Street address
Golestan Blvd., Ahvaz Golestan hospita-Generall operating room
City
Ahvaz
Postal code
Phone
+98 61 3221 6504
Fax
Email
vaziri.m@ajums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Farahzad Janatmakan
Position
Assistant Professor
Other areas of specialty/work
Street address
Golestan Blvd., Ahvaz Golestan hospital-General operating room
City
Ahvaz
Postal code
Phone

00

Fax

Email

Fjanatmakan@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mahshid Vaziri

Position

Resident of Anesthesiology

Other areas of specialty/work

Street address

Golestan Blvd., Ahvaz Golestan hospital-General operating room

City

Ahvaz

Postal code

Phone

+98 61 3221 6504

Fax

Email

vaziri.m@ajums.ac.ir

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