

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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, administered 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-General 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

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Person responsible for scientific inquiries

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Assistant Professor

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Full name of responsible person

Mahshid Vaziri

Position

Resident of Anesthesiology

Other areas of specialty/work

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Phone

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