

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparative study of the effect of two-dose infusion of 0.3 and 0.6 µg / kg dexmedetomidine during surgery on changes in hemodynamic parameters and pain in patients undergoing spinal surgery under general anesthesia

Protocol summary

Study aim

The aim of this study was to compare the effect of infusion of 0.3 and 0.6 µg / kg dexmedetomidine during surgery on changes in hemodynamic parameters and pain in patients undergoing spinal surgery under general anesthesia.

Design

In this triple blind randomized controlled clinical trial of phase 3, 81 patients who are candidates for spinal surgery are distributed in three groups of 27 patients. In the first and second groups, 0.3 and 0.6 micrograms per kilogram of dexmedetomidine, respectively, and in the third group with a similar volume of normal saline as an intravenous infusion at the time of induction of anesthesia. Hemodynamic parameters during surgery and recovery and severity of postoperative pain are evaluated and compared in three groups.

Settings and conduct

This randomized three-blind clinical trial study was performed in 2021 in Al-Zahra Hospital in Isfahan on patients who were candidates for spine surgery.

Participants/Inclusion and exclusion criteria

In this study, patients who are candidates for spinal surgery under general anesthesia, who are in the age range of 18 to 65 years and have no history of heart and liver and kidney disease and agree to participate in the study are included in the study.

Intervention groups

In this study, three groups enter the research. The first group: patients injected with 0.3 micrograms per kilogram of dexmedetomidine, the second group: under injected with 0.6 micrograms per kilogram of dexmedetomidine. Group 3: Under normal saline injection of the same volume as an intravenous infusion at the time of induction of anesthesia.

Main outcome variables

Blood pressure; heart rate; blood oxygen saturation; postoperative pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N53**

Registration date: **2021-03-15, 1399/12/25**

Registration timing: **prospective**

Last update: **2021-03-15, 1399/12/25**

Update count: **0**

Registration date

2021-03-15, 1399/12/25

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-03, 1400/01/14

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of two-dose infusion of 0.3 and 0.6 µg / kg dexmedetomidine during surgery on changes in hemodynamic parameters and pain in patients undergoing spinal surgery under general anesthesia

Public title

Comparison of injection of two different amounts of dexmedetomidine on blood pressure, heart rate and postoperative pain

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidate for spinal laminectomy under general anesthesia ASA(American Society of Anesthesiologists) 1 & 2 Patient consent to participate in the study

Exclusion criteria:

History of kidney and liver disease History of allergy to any anesthetic drug Heart failure or a history of myocardial infarction Drug and alcohol addiction or mental illness Pregnancy

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample sizeTarget sample size: **81****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients are distributed in three groups by simple random allocation method. To do this, the letter A is written on 27 cards, the letter B is written on 27 cards and the letter C is written on 27 cards, and all the cards are put in a box and shuffled well. At the time of each patient's visit, he / she is asked to take a card out of the box. According to the letter written on the card, the patient is assigned to the group of dexmedetomidine 0.3, dexmedetomidine 0.6 or control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study is done in three blinds. Patient researchers and analysts are unaware of patients being assigned to groups. The drugs are prepared by an operating room staff who is not in the study, in similar and coded

syringes, and are given to the researcher for injection. After analyzing the data, the codes are opened and the results are compiled accordingly.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Research deputy, Isfahan University of Medical Sciences, Hezar Jerib street

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Isfahan

Province

Isfahan

Postal code

8434193474

Approval date

2020-05-18, 1399/02/29

Ethics committee reference number

IR.MUI.MED.REC.1399.195

Health conditions studied**1****Description of health condition studied**

Disk herniation

ICD-10 code

M51:26

ICD-10 code description

Disk herniation

Primary outcomes**1****Description**

Blood pressure

Timepoint

Every half hour during surgery and recovery

Method of measurement

Pulse Oximeter

2**Description**

Hear rate

Timepoint

Every half hour during surgery and recovery

Method of measurement

Pulse Oximeter

3

Description

Percentage of blood oxygen saturation

Timepoint

Every half hour during surgery and recovery

Method of measurement

Pulse Oximeter

4

Description

Post operative pain

Timepoint

Every 30 minutes from the entrance to recovery and 2, 8, 24 and 48 hours after surgery

Method of measurement

Using a visual analog scale(VAS) that divides patients' pain intensity from zero to 10

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Patients receiving intravenous infusion of 0.3 µg / kg dexmedetomidine at the time of induction of anesthesia

Category

Treatment - Drugs

2

Description

Intervention group2: Patients receiving intravenous infusion of 0.6 µg / kg dexmedetomidine at the time of induction of anesthesia

Category

Treatment - Drugs

3

Description

Control group: Patients undergoing normal saline intravenous infusion with similar volume of intervention drugs at the time of induction of anesthesia.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Mahshad Rahimian

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahshad Rahimian

Position

Resident of Anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The plan belongs to a government agency and cannot be shared.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available