

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparing the effect of Dexmedetomidine and Remifentanyl on post operative pain control after spine surgery

Protocol summary

Study aim

Dexmedetomidine versus remifentanyl in post operative pain control after spine surgery.

Design

Clinical trial with double- blinded postoperative care and outcome assessment. Randomisation will be carried out using random digits table.

Settings and conduct

This double-blinded clinical trial will be done in Ahwas Golestan hospital. In this study patients and anesthesiologist will be kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18-65 ;elective spine surgery;ASA class 1and 2. Exclusion criteria: previous spine surgery; opium addiction;alcohol addiction; neurological, neuromuscular, psychological, pulmonary and cardiovascular diseases; prolonged usage of analgesic (cox-2 inhibitors); intra operative unpredictable events such as massive bleeding.

Intervention groups

Intervention group 1:Dexmedetomidine group(Dexmedetomidine single-dose before general anesthesia and dexmedetomidine infusion during operation), Intervention group 2:Remifentanyl group(Remifentanyl single_dose before general anesthesia and remifentanyl infusion during operation)

Main outcome variables

Pain; systolic blood pressure; diastolic blood pressure; heart rate; arterial oxygen saturation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191023045206N1**

Registration date: **2020-05-06, 1399/02/17**

Registration timing: **retrospective**

Last update: **2020-05-06, 1399/02/17**

Update count: **0**

Registration date

2020-05-06, 1399/02/17

Registrant information

Name

Mohammad Zafari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3333 3050

Email address

mohammad.zafari2@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-01, 1398/09/10

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Dexmedetomidine and Remifentanyl on post operative pain control after spine surgery

Public title

Dexmedetomidine versus remifentanyl in post operative pain control after spine surgery

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Elective surgery of spine age of 18-65 years ASA class 1,2

Exclusion criteria:
Previous spine surgery
Opium addiction
Alcohol addiction
Neurological disease
Neuromuscular disease
Psychological disease
Pulmonary disease
Cardiovascular disease
Analgesic consumer(cox-2 inhibitors)
Operative unpredictable events (massive bleeding)

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study spinal surgery patients will be divided to two groups receiving dexmedetomidine and remifentanyl in random using random digits table.

Blinding (investigator's opinion)
Double blinded

Blinding description
The anesthesiologist who has responsible for the patients management of anesthesia will administer the medicine (s) via coded syringes had been prepared previously and will not aware of the injected drug (dexmedetomidin or remifentanyl), and anesthesia nurse who is responsible for collection of patients information and study variables is unaware of the administered drug will record the check- list during surgery and in the recovery. Also the patient is unaware of the injected medicine.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahwaz University of Medical Sciences

Street address

Golestan hospital; Golestan avenue

City

Ahwaz

Province

Khouzestan

Postal code

6136763316

Approval date

2019-11-16, 1398/08/25

Ethics committee reference number

IR.AJUMS.REC.1398.593

Health conditions studied

1

Description of health condition studied

Post operative pain

ICD-10 code

R52.9

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

Pain

Timepoint

30, 60 and 120 minutes and 24 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Systolic blood pressure variance

Timepoint

30, 60 and 120 minutes and 24 hours after surgery

Method of measurement

blood pressure monitor

2

Description

Diastolic blood pressure variance

Timepoint

30, 60 and 120 minutes and 24 hours after surgery

Method of measurement

blood pressure monitoring

3

Description

Heart rate variance

Timepoint

30, 60 and 120 minutes and 24 hours after surgery

Method of measurement

heart rate monitoring

4

Description

O2 saturation variance

Timepoint

30, 60 and 120 minutes and 24 hours after surgery

Method of measurement

Pulseoxymetry

Intervention groups

1

Description

Intervention group1:serum ringer lactate 5 ml/kg,midazolam 0.02 mg/kg,fentanyl 2mcg/kg,propofol1.5 mg/kg,atracurium 0.5 mg/kg,morphine sulfate 0.1 mg/kg for induction and dexmedetomidine0.1mcg/kg in 10 minutes(Abureyhan _Iran co.) and for maintenance propofol 100 to 150 mcg/kg besides dexmedetomidine0.1mcg/kg/h will receive.

Category

Diagnosis

2

Description

Intervention group2:serum ringer lactate 5 ml/kg,midazolam 0.02 mg/kg,fentanyl 2mcg/kg,propofol1.5 mg/kg,atracurium 0.5 mg/kg,morphine sulfate 0.1 mg/kg for induction and remifentanyl bolus dose(Abureyhan _Iran co.) 1 mcg/kg and for maintenance propofol 100 to 150 mcg/kg besides 1 mcg/kg/min remifentanyl will receive.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahwaz Golestan hospital

Full name of responsible person

Mohammad Zafari

Street address

Golestan avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Farahzad Jannatmakan

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Farahzad Janatmakan

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Nozar Nassajian

Position

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

data after the end of study will be available.

When the data will become available and for how long

from 2021

To whom data/document is available

physicians

Under which criteria data/document could be used

using for future studies.

From where data/document is obtainable

send E-Mail to Mohammad.zafari2@yahoo.com

What processes are involved for a request to access data/document

filling the study request form

Comments