Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

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

Protocol summary

Study aim
Dexmedetomidine versus remifentanil 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, psycological, 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 durig operation),Intervention group 2:Remifentanil group(Remifentanil single_dose before general anesthesia and remifentanil 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

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Iran (Islamic Republic of)

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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 Remifentanil on post operative pain control after spine surgery

Public title
Dexmedetomidine versus remifentanil 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 devided to two groups recieving dexmedetomidine and remifentanile 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 remifentanile), 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 pressue monitor

2

Description
Diastolic blood pressue 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,atracuriom 0.5 mg/kg,morphine sulfate 0.1 mg/kg for induction and dexmedetomidine0.1mcg/kg in 10 minutes(Abureyhan _Iran co.) and for maintnance propofol 100 to 150 mcg/kg besides dexmedetomidine0.1mcg/kg/h will recieve.
Category
Diagnosis

2

Description
Intervention group2:serum ringer lactate 5 ml/kg,midazolam 0.02 mg/kg,fentanyl 2mcg/kg,propofol1.5 mg/kg,atracuriom 0.5 mg/kg,morphine sulfate 0.1 mg/kg for induction and remifentanile bollus dose(Abureyhan _Iran co.) 1 mcg/kg and for maintnance propofol 100 to 150 mcg/kg besides 1 mcg/kg/min remifentanile will recieve.
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
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Full name of responsible person
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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
Anesthesiology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

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Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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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 avalable.

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 reguest form

Comments