

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the effect of regional analgesia with dexamethasone and dexmedetomidine on spinal surgery

Protocol summary

Study aim

Comparison of the effect of regional analgesia with dexamethasone and dexmedetomidine on spinal surgery

Design

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 120 patients, computer-generated random numbers were used for randomization.

Settings and conduct

In the operating rooms of Ahvaz Golestan Hospital, after anesthetizing the patient with anesthetics including midazolam, fentanyl, sodium thiopental and atracurium and then intubating the patient, at the rate of 0.1 mg per kilogram of body weight, the patients were divided into 3 main groups and they would be studied.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 16 to 65 year old patients who are candidated for discopathy surgery at ASA I-II level who will undergo 1 or 2 level posterior lumbar spine surgery. Absence of history of allergy to Dexa and Dexm drugs, absence of severe heart and lung disease, arrhythmia, liver and kidney failure or mental illness, absence of history of chronic pain or long-term history of taking painkillers and absence of drug addiction are other criterias that will be included in the study.

Intervention groups

Patients are divided into 3 groups. At the end of the operation, for one group, 0.2 mg/kg dexamethasone on gelophene, for the next group, 0.2 mg/kg dexmedetomidine on gelophene and for the third group, normal saline with gelophene is placed in the operation site before suturing the operation site. At the end of the operation, after the extubation of the patient, the postoperative pain will be evaluated every 30 minutes for the first 2 hours and then every 2 hours until 24 hours using a 10 cm VAS.

Main outcome variables

amount of pain based on VAS scale; duration of analgesia; amount of used sedatives

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230530058342N1**

Registration date: **2023-10-05, 1402/07/13**

Registration timing: **prospective**

Last update: **2023-10-05, 1402/07/13**

Update count: **0**

Registration date

2023-10-05, 1402/07/13

Registrant information

Name

Sina Mokhtarbaf

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-06, 1402/08/15

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of regional analgesia with dexamethasone and dexmedetomidine on spinal surgery	
Public title	The effect of regional analgesia with dexamethasone and dexmedetomidine
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: All patients who are going to undergo posterior 1 or 2 lumbar spine surgery at ASA I-II level Exclusion criteria: History of oversensitivity to Dexamethasone History of oversensitivity to Dexmedetomidine History of severe Cardiac disease History of severe Pulmonary disease History or presence of arrhythmias Kidney failure Liver failure Psychiatric disorder History of chronic pain Addiction to opioids History of longterm use of sedative medications
Age	From 16 years old to 65 years old
Gender	Both
Phase	3
Groups that have been masked	• Participant • Care provider • Investigator • Outcome assessor
Sample size	Target sample size: 120
Randomization (investigator's opinion)	Randomized
Randomization description	Entered patients will be randomly divided into three groups with a ratio of 1:1:1 using a table of random numbers generated by the computer. The distribution results will be sealed in a sealed envelope and kept by the research manager. On the day of the procedure, the principal reasercher will hand over the envelope to the anesthesia assistant to prepare the test fluid. In fact, the patients and the anesthesia assistant will be blinded to the type of used adjuvant (Dexmedetomidine or Dexamethasone or placebo).
Blinding (investigator's opinion)	Double blinded
Blinding description	Entered patients will be randomly divided into three groups with a ratio of 1:1:1 using a table of random numbers generated by the computer. The distribution results will be sealed in a sealed envelope and kept by the research manager. On the day of the procedure, the principal reasercher will hand over the envelope to the anesthesia assistant to prepare the test fluid. In fact, the patients and the anesthesia assistant will be blinded to the type of used adjuvant (Dexmedetomidine or Dexamethasone or placebo).
Placebo	Used

Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	1 Ethics committee Name of ethics committee Ethics committee of Golestan Hospital at Ahvaz University of Medical Sciences Street address Golestan Hospital, Golestan City Ahvaz Province Khouzestan Postal code 6155965138 Approval date 2023-03-14, 1401/12/23 Ethics committee reference number IR.AJUMS.HGOLESTAN.REC.1401.186
Health conditions studied	1 Description of health condition studied Postoperative Pain after discopathy surgery ICD-10 code G89.18 ICD-10 code description Other acute postprocedural pain
Primary outcomes	1 Description Pain level based on VAS 10 scale Timepoint Postoperative pain will be assessed every 30 minutes for the first 2 hours and then every 2 hours up to 24 hours using a 10 cm VAS. Method of measurement VAS 10 Scale
Secondary outcomes	1 Description The time that the first pain killer is requested by the patient Timepoint

As soon as the first painkiller is requested by the patient

Method of measurement
Based on the time that the first pain killer is requested by the patient

2

Description
The total amount of narcotics consumed by the patient in the first 24 hours after the operation

Timepoint
Every 30 minutes for the first 2 hours and then every 2 hours for 24 hours

Method of measurement
Based on the amount of narcotics consumed based on milligrams

Intervention groups

1

Description
Intervention group 1: For the dexamethasone group, 0.2 mg/kg of dexamethasone is placed inside the gelophane on the operation site before suturing the operation site. Each ampule of dexamethasone contains 8 mg and belongs to Alborz Daru Company.

Category
Rehabilitation

2

Description
Intervention group 2: For the dexmedetomidine group, 0.2mg/kg of dexmedetomidine is placed inside the gelophane on the operation site before suturing the operation site. Each vial of dexmedetomidine contains 2 cc (200 micrograms) and belongs to Elixir company.

Category
Rehabilitation

3

Description
Control group: For the control group, normal saline with gelophane is placed in the operation site before suturing the operation site.

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Golestan Hospital
Full name of responsible person
Mahshid Vaziri
Street address
Golestan Hospital, Golestan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnosh Zakerkish
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Ahvaz Jundi Shapour University of medical Sciences, Golestan
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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
Mahshid Vaziri
Position
Assistant Professor
Latest degree
Specialist

Other areas of specialty/work

Anesthesiology

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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)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available