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 gelophane 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)

Phone
+98 61 3392 4672

Email address
mokhtarbaf.s@ajums.ac.ir

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 Pcychiatric 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

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Phone

+98 61 3374 3001

Email

golestanh@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Street address

Ahvaz Jundi Shapour University of medical Sciences, Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3311 0000

Email

info@ajums.ac.ir

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
Street address
Ahvaz Golestan Hospital, Golestan
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Phone
+98 61 3374 3037
Email
vaziri-m@ajums.ac.ir

Person responsible for scientific 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
Street address
Ahvaz Golestan Hospital, Golestan
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Phone
+98 61 3374 3037
Email
vaziri-m@ajums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Sina Mokhtarbaf
Position
Medical Intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
Ahvaz Golestan Hospital, Golestan
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3311 0000
Email
mokhtarbaf.s@ajums.ac.ir

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