Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the postoperative epidural analgesic efficacy between epidural catheter and surgical hemo-vac drain with epidural injection capability in posterior lumbar surgeries

Protocol summary

Study aim
Evaluating two different techniques of epidural administration of 4 mg dexamethasone and ropivacaine 0.2% with epinephrine (1:200,000) for pain management following posterior lumbar surgeries

Design
Randomized, nonblinded, controlled clinical trial with two parallel groups, on 52 posterior lumbar spine surgery instrumentation candidates, using the block randomization method

Settings and conduct
Randomized clinical trial performed on the posterior lumbar spine surgery instrumentation candidates of Shahid Madani Hospital, Karaj. Patients are randomly divided into two groups consisting of quadruple blocks using the nonblinded block randomization method.After the operation, Hemo vac drain capable of epidural drug injection is placed inside the surgical incision. The epidural injection is repeated every 6 hours until 48 hours after the surgery. Intravenous morphine (0.05 mg/kg) is injected for pain scores higher than 3. Patients are asked to state the level of their pain.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 to 65; candidate for instrumentation in posterior lumbar spine surgeries; ASA class I,II Exclusion criteria: infections; tumors; fracture in the area of surgery; mental retardation; preoperative neurological disorders; allergy to anesthetic drugs; pregnancy

Intervention groups
Control group: dexamethasone (4 mg), ropivacaine (0.2%, 25 ml), and epinephrine (1:200000) using an epidural catheter. Intervention group: dexamethasone (4 mg), ropivacaine (0.2%, 25 ml), and epinephrine (1:200000) using Hemo vac drain with epidural drug delivery capability The drain is equipped with two separate joint lumens (along with each other). One lumen delivers the drug while the other drains the fluids from the wound.

Main outcome variables
The level of pain; Patient satisfaction; The duration of analgesia; The time of starting to move; The amount of postoperative bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210829052319N1**
Registration date: **2022-03-17, 1400/12/26**
Registration timing: **prospective**

Last update: **2022-03-17, 1400/12/26**
Update count: **0**

Registration date
2022-03-17, 1400/12/26

Registrant information

Name
Mehdi Rezaee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 26 3420 7972

Email address
m.rezaei@abzums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-04, 1401/01/15

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the postoperative epidural analgesic efficacy between epidural catheter and surgical hemo-vac drain with epidural injection capability in posterior lumbar surgeries

Public title

Comparison of efficacy of two methods of epidural analgesia

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

written consent to participate in the study age 18 to 65 candidate for instrumentation in posterior lumbar spine surgeries ASA class I-II

Exclusion criteria:

patients withholding consent infection tumor fracture in the area of surgery speech impairments mental retardation preoperative neurological disorders allergy to anesthetic drugs patients with pacemaker patients that have used ropivacaine, opioids, and NSAIDs one week before the surgery failure in epidural catheter placement during the surgery pregnancy nausea and vomiting severe hemodynamic changes such as bradycardia or blood pressure drop higher than 30% of average blood pressure seizure severe headache progressive paresthesia of the lower limbs decreased level of consciousness changes in respiratory rate and order

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups consisting of quadruple blocks using the non-blinded block randomization method

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Ethics Committee Office, Second Floor, Deputy of Research and Technology, Saffarian Alley, 45 Meters Golshahr Ave

City

Karaj

Province

Alborz

Postal code

3198764653

Approval date

2021-12-06, 1400/09/15

Ethics committee reference number

IR.ABZUMS.REC.1400.260

Health conditions studied

1

Description of health condition studied

بی دردی اپیدورال بعد از اعمال جراحی لومبار خلفی

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

The level of pain at the state of rest

Timepoint

Before the surgery, 8, 16, 24, 32, 40, 48 hours, and 4 months after the surgery

Method of measurement

Asking the patient, based on visual analogue scale (0=no pain, 1-3=mild pain, 4-7=moderate pain, and 8-10=severe pain)

2

Description

The level of pain at the state of motion

Timepoint

Before the surgery, 8, 16, 24, 32, 40, 48 hours, and 4 months after the surgery

Method of measurement

Asking the patient, based on visual analogue scale (0=no pain, 1-3=mild pain, 4-7=moderate pain, and

8-10=severe pain)

3

Description
The level of patient satisfaction with pain management
Timepoint
Upon discharge from the hospital, and 4 months after the surgery
Method of measurement
Asking the patient, based on a 0 to 10 score (0=not satisfied, 1-3=relative satisfaction, 4-7=high level of satisfaction, and 8-10=completely satisfied)

4

Description
The level of surgeon satisfaction (i.e., operating environment and the rate of bleeding)
Timepoint
At the end of the surgery
Method of measurement
Asking the surgeon, based on a 0 to 10 score (0-2=not satisfied, 3-5=low level of satisfaction, 6-8=relative satisfaction, and 9-10=completely satisfied)

5

Description
The time of starting to move
Timepoint
The time of starting to move
Method of measurement
Asking the nurse

6

Description
The time to first analgesic request
Timepoint
The time to first analgesic request
Method of measurement
Asking the nurse

7

Description
The amount of postoperative bleeding
Timepoint
48 hours after the surgery
Method of measurement
Evaluation of blood volume in Hemovac drain during the first 48 hours after surgery minus the volume of drug solution injected into the surgical wound

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: dexamethasone (4 mg) + ropivacaine (0.2%, 25 ml) + epinephrine (1:200000) using Hemo-vac drain with epidural drug delivery capability. The epidural injection is repeated every 6 hours until 48 hours after the surgery.
Category
Treatment - Devices

2

Description
Control group: dexamethasone (4 mg) + ropivacaine (0.2%, 25 ml) + epinephrine (1:200000) using an epidural catheter. The epidural injection is repeated every 6 hours until 48 hours after the surgery.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani hospital
Full name of responsible person
Mehdi Rezaee
Street address
Shahid Madani Square, Jahanshahr
City
Karaj
Province
Alborz
Postal code
4469331437
Phone
+98 26 3442 7001
Fax
+98 26 3442 6979
Email
m.rezaei@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Hatam Godini
Street address
Alborz University of medical Sciences, Administrative town, North Taleghani Bleuvard , Taleghani Square
City
Karaj
Province
Alborz
Postal code

3149779453

Phone
+98 26 3419 7000

Email
Info@abzums.ac.ir

Web page address
https://www.abzums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Karaj 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
Karaj University of Medical Sciences

Full name of responsible person
Mehdi Rezaee

Position
Assistant professor of anesthesia

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Unit 5 , Floor 3 , No. 27 , West Rahimi Ave. , Mahan Blvd , Jahanshahr , Karaj

City
Karaj

Province
Alborz

Postal code
3143754843

Phone
+98 26 3420 7972

Fax

Email
m.rezaei@abzums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
Mehdi Rezaee

Position
Assistant professor of anesthesia

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Person responsible for updating data

Contact

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Fax

Email
m.rezaei@abzums.ac.ir

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic data and measured investigation variables will be accessible.

When the data will become available and for how long

June. 21 2022 to Sep. 22, 2022

To whom data/document is available

Only accredited investigators or resrarch institutes

Under which criteria data/document could be used

Data analysis permission is given to confirm the outcomes of the study and outcomes other than mentioned in this study.

From where data/document is obtainable

Mehdi Rezaee, Anesthesiology Departmant, Madani Hospital, Karaj.Alborz

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

Email to : m.rezaei@abzums.ac .ir and request for investigation data، following confirmation of the individual's or institute's identity the data will become accessible through mailing.

Comments