Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparing the effects of bupivacaine and bupivacaine-methylprednisolone in ultrasound guided erector spinae plane block on postoerative pain in Lumbar spine surgery

Protocol summary

Study aim

Comparing the effects of bupivacaine and bupivacaine-methylprednisolone in ultrasound guided erector spinae plane block on post operative pain in Lumbar spine surgery

Design

Clinical trial with control and intervention group, single blind, on 64 patients, randomized with sealed envelope.

Settings and conduct

Patients referred to Luqman Hospital are divided into two intervention and control groups of 32 people by block randomization. After anesthesia with the same method, both groups will be placed in the prone position before the surgery under ultrasound guidance under bilateral erector spina block at the level of the surgical site. Paramedian sagittal ultrasound probe, about 2 cm outside the spinous processes, we find the transverse process on the same side. We insert the needle caudal to the cranial so that the tip of the needle hits the transverse process. If the needle site is suitable, 20 cc of bupivacaine-methylprednisolone will be injected in the intervention group and 20 cc of bupivacaine 0.25% in the control group. Isoflurane and opioid consumption during surgery, pain, nausea and vomiting during recovery and sugar measurement The blood will be determined up to 24 hours later, as well as the pain level of the patient up to one month.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients 18-65 years old; Normal kidney and liver function; ASA score 1-2; Patient consent ; No history of allergies to local anesthetics; No drug addiction Exclusion criteria:, Increase the scope of surgery to more than three level ,time of surgery for more than 6 hours; No diabetes

Intervention groups

The intervention group, after anesthesia and changing to the prone position, ,are subjected to erector spinae block with bupivacaine-methylprednisolone, and the control group are subjected to block with bupivacaine

Main outcome variables

Consumption of isofluran , opioids, pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210415050983N6**
Registration date: **2024-04-18, 1403/01/30**
Registration timing: **prospective**

Last update: **2024-04-18, 1403/01/30**
Update count: **0**

Registration date

2024-04-18, 1403/01/30

Registrant information

Name

Sogol Asgari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8836 3185

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-21, 1403/03/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of bupivacaine and bupivacaine-methylprednisolone in ultrasound guided erector spinae plane block on postoerative pain in Lumbar spine surgery

Public title

Comparing the effects of bupivacaine and bupivacaine-methylprednisolone in ultrasound guided erector spinae plane block on postoerative pain in Lumbar spine surgery

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 18-65 years old are candidates for two or three level spine surgery ASA score 1-2 Normal kidney and liver function Patient consent to perform the block No history of allergies to local anesthetics No drug addiction No diabetes

Exclusion criteria:

Increase the scope of surgery to more than three level Extending the length of surgery for more than 6 hours Block site infection or systemic History of anticoagulant use

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Randomized Blocks :In this method, 10 random blocks are generated by computer. Each block includes 5 people in the intervention group and 5 people in the control group. The order of these people is randomly arranged by computer and people are assigned to groups in the same way. At the end of each block, a new block of 10 is produced and this process will continue until the final sample volume is reached.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants in the study are unaware of the groupings because the intervention is performed after anesthesia. The patient's clinical caregiver, the evaluator and recorder of the results, and the data analyzer are not aware of the grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice for Research and Technology, Shahid Beheshti University of Medical Sciences

Street address

Velenjak, Yemen Street, Shahid Shahriari Square

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Tehran

Province

Tehran

Postal code

1985717443

Approval date

2024-01-24, 1402/11/04

Ethics committee reference number

IR.SBMU.MSP.REC.1402.575

Health conditions studied

1

Description of health condition studied

Lumbar discopathy

ICD-10 code

M51.36

ICD-10 code description

Other intervertebral disc degeneration, lumbar region

Primary outcomes

1

Description

Intraoperative isoflurane Consumption in tow groups

Timepoint

Before the start of anesthesia and after the end of anesthesia

Method of measurement

By a graduated glass based on mL

2

Description

Intraoperative fentanyl consumption in the two groups

Timepoint

End of surgery

Method of measurement

Dosage consumed based on mcg

3

Description
Pain after surgery
Timepoint
0, 1 and 6 hours after surgery and one month after surgery
Method of measurement
NRS

4

Description
blood sugar
Timepoint
After surgery up to 24 months
Method of measurement
Blood test

Secondary outcomes

1

Description
nausea and vomiting
Timepoint
0, 1 and 6 hours after surgery
Method of measurement
Ask the patient

Intervention groups

1

Description
Control group: After anesthesia and change of position to peron before surgery, in sterile conditions, using peripheral nerve block needle (stimuQuik, ARROW use) with sonosite-Nerve Ultrasound system under the erector spina block One-sided and each-sided injection of 20 ml of 0.25% bupivacaine was performed by a trained anesthesiologist in accordance with standard guidelines.A 5-8MHz liner probe is used for nerve block ultrasound guides. After selecting the target process transducer, the sagittal paramedic prop is placed about 2 cm outside the spinous processes so that the process transducer can be seen in the same direction. Insert the needle inplean the codal from the cranial to cudal until the tip of the needle hits the process transducer. 1-2 cc of local anesthetic is injected to ensure the correct location of the needle. If the location of the needle is suitable, the medicine is injected. The needle point is towards the posterior and inferior side.
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group: After anesthesia and change of position to peron before surgery, in sterile conditions, using peripheral nerve block needle (stimuQuik, ARROW use) with sonosite-Nerve Ultrasound system under the erector spina block One-sided and each-sided injection of 20 ml of Bupivacaine and methylprednisolone 40 was performed by a trained anesthesiologist in accordance with standard guidelines.A 5-8MHz liner probe is used for nerve block ultrasound guides. After selecting the target process transducer, the sagittal paramedic prop is placed about 2 cm outside the spinous processes so that the process transducer can be seen in the same direction. Insert the needle inplean the codal from the cranial to cudal until the tip of the needle hits the process transducer. 1-2 cc of local anesthetic is injected to ensure the correct location of the needle. If the location of the needle is suitable, the medicine is injected. The needle point is towards the posterior and inferior side.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
Sogol Asgari
Street address
South Kargar St. - Kamali St. - Special St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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?
No

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Sogol Asgari

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Position
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Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

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Position
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Other areas of specialty/work
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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