# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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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**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

**City**

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**
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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?**
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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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