

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Comparing the effects of bupivacaine and Meperidine in ultrasound guided erector spinae plane block on hypnotic and opi consumption and post operative pain and shivering and PONV during lumbar spine surgery

#### Protocol summary

##### Study aim

Comparing the effects of bupivacaine and Meperidine in ultrasound guided erector spinae plane block on hypnotic consumption and post operative pain during 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 Lughman 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 spinae 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 location of the needle is suitable, In the intervention group, 20 cc of meperidine and 20 cc of bupivacaine 0.25% were injected in the control group. The amount of isoflurane and opioids used during the operation, pain, Nausea, vomiting and shivering at 0, 1 and 6 hours will be recorded. The data collector and data analyst are not aware of the groupings.

##### 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 levels, time of surgery for more than 6 hours

##### Intervention groups

The intervention group, after anesthesia and changing to the prone position, before the start of surgery, are

subjected to erector spinae block with meperidine, and the control group are subjected to block with bupivacaine

##### Main outcome variables

Consumption of isoflurane, opioids, pain score, nausea, vomiting, shivering

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210415050983N5**

Registration date: **2023-09-21, 1402/06/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-09-21, 1402/06/30**

Update count: **0**

##### Registration date

2023-09-21, 1402/06/30

##### Registrant information

##### Name

Sogol Asgari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8836 3185

##### Email address

drasgari98429@sbmu.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2023-09-16, 1402/06/25

##### Expected recruitment end date

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| <div>2023-12-16, 1402/09/25</div> <div><b>Actual recruitment start date</b></div> <div>empty</div> <div><b>Actual recruitment end date</b></div> <div>empty</div> <div><b>Trial completion date</b></div> <div>empty</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <div>The patient's clinical caregiver, the evaluator and recorder of the results, and the data analyzer are not aware of the grouping.</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <div><b>Scientific title</b></div> <div>Comparing the effects of bupivacaine and Meperidine in ultrasound guided erector spinae plane block on hypnotic and opi consumption and post operative pain and shivering and PONV during lumbar spine surgery</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <div><b>Placebo</b></div> <div>Not used</div> <div><b>Assignment</b></div> <div>Parallel</div> <div><b>Other design features</b></div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <div><b>Public title</b></div> <div>Comparing the effects of bupivacaine and Meperidine in ultrasound guided erector spinae plane block on hypnotic consumption and post operative pain during lumbar spine surgery</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <div><b>Secondary Ids</b></div> <div>empty</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <div><b>Public title</b></div> <div>Comparing the effects of bupivacaine and Meperidine in ultrasound guided erector spinae plane block on hypnotic consumption and post operative pain during lumbar spine surgery</div> <div><b>Purpose</b></div> <div>Other</div> <div><b>Inclusion/Exclusion criteria</b></div> <div><b>Inclusion criteria:</b></div> <div>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</div> <div><b>Exclusion criteria:</b></div> <div>Increase the scope of surgery to more than three level<br/>Extending the length of surgery for more than 6 hours<br/>Block site infection or systemic History of anticoagulant use</div> <div><b>Age</b></div> <div>From <b>18 years</b> old to <b>65 years</b> old</div> <div><b>Gender</b></div> <div>Both</div> <div><b>Phase</b></div> <div>3</div> | <div><b>Ethics committees</b></div> <div><u>1</u></div> <div><b>Ethics committee</b></div> <div><b>Name of ethics committee</b></div> <div>Vice for Research and Technology, Shahid Beheshti University of Medical Sciences</div> <div><b>Street address</b></div> <div>Velenjak, Yemen Street, Shahid Shahriari Square</div> <div><b>City</b></div> <div>Tehran</div> <div><b>Province</b></div> <div>Tehran</div> <div><b>Postal code</b></div> <div>1985717443</div> <div><b>Approval date</b></div> <div>2023-09-13, 1402/06/22</div> <div><b>Ethics committee reference number</b></div> <div>IR.SBMU.RETECH.REC.1402.325</div> |
| <div><b>Groups that have been masked</b></div> <div> <ul style="list-style-type: none"> <li>Participant</li> <li>Care provider</li> <li>Outcome assessor</li> <li>Data analyser</li> </ul> </div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <div><b>Health conditions studied</b></div> <div><u>1</u></div> <div><b>Description of health condition studied</b></div> <div>Lumbar discopathy</div> <div><b>ICD-10 code</b></div> <div>M51.36</div> <div><b>ICD-10 code description</b></div> <div>Other intervertebral disc degeneration, lumbar region</div>                                                                                                                                                                                                                                                                                                                    |
| <div><b>Sample size</b></div> <div>Target sample size: <b>64</b></div> <div><b>Randomization (investigator's opinion)</b></div> <div>Randomized</div> <div><b>Randomization description</b></div> <div>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.</div>                                                                                                                                                                                                                                                                                                                                                           | <div><b>Primary outcomes</b></div> <div><u>1</u></div> <div><b>Description</b></div> <div>Intraoperative isoflurane Consumption in tow groups</div> <div><b>Timepoint</b></div> <div>Before the start of anesthesia and after the end of anesthesia</div> <div><b>Method of measurement</b></div> <div>By a graduated glass based on mL</div>                                                                                                                                                                                                                                                                                        |
| <div><b>Blinding (investigator's opinion)</b></div> <div>Single blinded</div> <div><b>Blinding description</b></div> <div>Participants in the study are unaware of the groupings because the intervention is performed after anesthesia.</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <div><u>2</u></div> <div><b>Description</b></div> <div>Intraoperative fentanyl consumption in the two groups</div> <div><b>Timepoint</b></div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

End of surgery  
**Method of measurement**  
Dosage consumed based on mcg

### 3

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

## 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: 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 meperidine 50mg 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.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1333635445  
**Phone**  
+98 21 5102 5291  
**Email**  
drasgari98429@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Luqman Hakim Hospital Research Center  
**Street address**  
Velenjak, Yemen Street, Shahid Shahriari Square  
**City**  
tehran  
**Province**  
Tehran  
**Postal code**  
1985717443  
**Phone**  
+98 21 23871  
**Email**  
ms@sbmu.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shahid Beheshti University of Medical Sciences

**Proportion provided by this source**

1

**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**

Seyed Sammehdi Hosseininasab

**Position**

Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

South Kargar St. - Kamali St. - Special St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1333635445

**Phone**

+98 21 2282 9227

**Email**

sam.hn617@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyed Sammehdi Hosseininasab

**Position**

Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

South Kargar St. - Kamali St. - Special St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1333635445

**Phone**

+98 21 2282 9227

**Email**

sam.hn617@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Massoud Nashibi

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

South Kargar St. Kamali St. Special Loghman Hakim Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1333635445

**Phone**

+98 21 5541 9005

**Email**

masoudnashibi@yahoo.com

**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