

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 level, 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

2023-12-16, 1402/09/25 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty	The patient's clinical caregiver, the evaluator and recorder of the results, and the data analyzer are not aware of the grouping.
Scientific title 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	Placebo Not used Assignment Parallel Other design features
Public title 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	Secondary Ids empty
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 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	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 2023-09-13, 1402/06/22 Ethics committee reference number IR.SBMU.RETECH.REC.1402.325
Groups that have been masked - Participant - Care provider - Outcome assessor - Data analyser	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
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.	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
Blinding (investigator's opinion) Single blinded Blinding description Participants in the study are unaware of the groupings because the intervention is performed after anesthesia.	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
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

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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