

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The Efficacy of Ultrasound Guided Erector spina block in postoperative pain reduction in lumbar spinal surgeries

Protocol summary

Study aim

Evaluation of effectiveness of Erector Spina block in pain reduction after lumbar spinal laminectomy surgery

Design

Two parallel group randomized trial with blinded participants and outcome assessment. Each group contains 20 samples randomized by software.

Settings and conduct

In this study all 18-75 y/o patients candidates for laminectomy surgery in Loghman hospital in Tehran will be divided randomly in two groups of case and control. Each group contains 20 samples. After induction of anesthesia and changing the position to prone the case group receive erector spina block under ultrasound guide with bupivacaine 0.25 % , 20 cc each side . The Control group will receive exactly the same anesthetic regimen as Case group. After surgery the pain score will be recorded in defined intervals. Also opioid consumption in first 24 hour after surgery will be recorded. We will report the results after analyzing the date.

Participants/Inclusion and exclusion criteria

All 18 to 75 y/o patients candidates for 1-3 level lumbar spinal laminectomy surgery with normal renal and hepatic function and ASA score 1-2 Who has not history of addiction nor allergy to local anesthetics and mental disorders will participate in this trial.

Intervention groups

After induction of anesthesia and changing the position to prone the case group receive erector spina block under ultrasound guide with bupivacaine 0.25 % , 20 cc each side . The Control group will receive exactly the same anesthetic regimen as Case group.

Main outcome variables

Pain score in defined intervals after surgery ; Opioid consumption in first 24 hour after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200628047936N1**

Registration date: **2020-09-27, 1399/07/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-27, 1399/07/06**

Update count: **0**

Registration date

2020-09-27, 1399/07/06

Registrant information

Name

Arash Tafrishinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 4715

Email address

arashtafrishi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-05, 1399/06/15

Expected recruitment end date

2020-10-21, 1399/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of Ultrasound Guided Erector spina block in postoperative pain reduction in lumbar spinal surgeries

Public title

Erector spina block in lumbar spinal surgery

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

All candidated 18-75 y/o patients for spinal lumbar surgery patients with normal hepatic and renal function ASA score 1-2

Exclusion criteria:

addiction BMI more than 35 or less than 16 allergy to local anesthetics mental disorders

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

All the participants will be divided randomly by using random number table generated by excel software into two groups of intervention and control. Forty patients will participate in this study and 20 of them will be allocated to intervention and the other 20 will enter control group based on randomization numbers which will be generated by excel software.

Blinding (investigator's opinion)

Double blinded

Blinding description

All participants and also data recording personal who will not be the same person who performs block, will not be informed about the group of each case.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti Medical University
کمیته اخلاق دانشگاه علوم

Street address

Loghman Hakim Hospital, Makhsus Ave., South Kargar Ave.

City

Tehran

Province

Tehran

Postal code

1333625445

Approval date

2020-07-12, 1399/04/22

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.394

Health conditions studied**1****Description of health condition studied**

Pain control after spinal surgery

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes**1****Description**

Postop pain score in defined intervals

Timepoint

1, 2 , 4, 6, 12, 24 Hours after surgery

Method of measurement

Pain scale chart (NRS)

2**Description**

Opioid consumption in first postop 24 hours

Timepoint

First 24 hours

Method of measurement

Amount of Opioid consumption recorded by nurse

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group:After induction of anesthesia and changing the position to prone the case group receive erector spina block under ultrasound guide with bupivacaine 0.25 % , 20 cc each side

Category

Other

2**Description**

Control group: Due to ethics committee suggestion, we

will not perform Erector Spinae block with placebo.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim hospital

Full name of responsible person

Arash Tafrishinejad

Street address

Loghman hospital, Makhsus St. , South Kargar Ave.

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Phone

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Email

loghman.hospital@sbmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Aarabi Ave., Yaman Ave., Chamran Blv

City

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Province

Tehran

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1983969411

Phone

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Email

zarghi@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

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

Arash Tafrishinejad

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Name of organization / entity

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Person responsible for updating data

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Fax**Email**

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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

All data and results will be reachable without identification info.

When the data will become available and for how long

Data will be reachable 3 month after publication

To whom data/document is available

All academic researchers

Under which criteria data/document could be used

Data can be used only for research and scientific purposes.

From where data/document is obtainable

Requests should be sent via Email to
arashtafrishi@gmail.com

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

Requests should be sent via Email .We will try to provide requested data in 1 month.

Comments