

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of postoperative analgesia following wound infiltration with Bupivacaine 0.25 solution after posterior lumbar spine surgeries

Protocol summary

Study aim

Evaluating the effect of Bupivacaine for the purpose of analgesia in patients whom underwent lumbar spine surgery

Design

Three arms parallel clinical trial including one control group and two case groups, triple blinded study, randomized, with sample size of 90 patients (3 * 30). For randomization, the Random Allocation Software will be used.

Settings and conduct

The place for conducting the research is Shahid Madani hospital in Karaj. The pain of patients' surgery site will be measured using Visual Analogue Scale (VAS) method and at specific times after surgery. The patients, the physician who evaluates the pain and the analyzer won't be aware of the patients' groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years old with spinal degenerative damage who undergo lumbar spine surgery. Exclusion criteria: No consent for participation, history of opioid addiction, any contraindication for drug infiltration, any history of allergic reaction to the drugs used in this project, chronic pain syndromes, history of seizure.

Intervention groups

1. Control group 2. Patients who receive Bupivacaine in their wounds after surgery 3. Patients who receive Bupivacaine plus Epinephrine in their wounds after surgery

Main outcome variables

VAS score for the pain of surgery site

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210213050348N2**

Registration date: **2021-09-01, 1400/06/10**

Registration timing: **prospective**

Last update: **2021-09-01, 1400/06/10**

Update count: **0**

Registration date

2021-09-01, 1400/06/10

Registrant information

Name

Arman Maghoul

Name of organization / entity

Alborz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 2276 1912

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arman.maghoul@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-12, 1400/06/21

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of postoperative analgesia following wound infiltration with Bupivacaine 0.25 solution after posterior lumbar spine surgeries

Public title

Evaluation of analgesia following Bupivacaine use in spine surgeries

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients over 18 years old whom are cases of degenerative damage to spine and undergo lumbar spine surgery.
Exclusion criteria:
 No consent for being in this study. Addiction to opioids. Any contraindications for drug infiltration. Any history indicative of allergic reaction to the drugs used in this study. Chronic pain syndromes. History of seizure.

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
First, a number is assigned to each participant and then the numbers are evenly divided into three blocks of control, Bupivacaine and Bupivacaine-Epinephrine by Random allocation software using simple block randomization method. For this purpose, after installing the program, we determine the number of groups, the sample size and the name of each group. Then, the software places patients with different codes in different groups according to the size of the groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The patient won't be aware of his/her study group after signing the consent form. The physician whom evaluates the outcome in the patient won't be present at the patient's operation and is not aware of the patient's study group. The data will be encrypted and the analyzer won't be aware of the patients' study groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethichs committee of Alborz University of Medical Sciences
Street address
 Alborz University of Medical Sciences, North Taleghani Blvd. , Taleghani Sq. , Karaj
City
 Karaj
Province
 Alborz
Postal code
 3149779453
Approval date
 2021-03-08, 1399/12/18
Ethics committee reference number
 IR.ABZUMS.REC.1400.002

Health conditions studied

1

Description of health condition studied
Spine degenerative damage
ICD-10 code
 M51.35
ICD-10 code description
 Other intervertebral disc degeneration, thoracolumbar region

Primary outcomes

1

Description
Visual Analogue Scale (VAS)score for surgical site pain
Timepoint
 6, 12 and 24 hours after surgery
Method of measurement
 By asking the patient to point out his/her pain degree on the VAS chart

Secondary outcomes
empty

Intervention groups

1

Description
Control group: Bupivacaine won't be injected into these patients
Category
 Treatment - Drugs

2

Description
Intervention group one: Bupivacaine. 30 cc of 0.25%

Bupivacaine solution will be infiltrated into the wound of the surgery after the operation is done.

Category

Treatment - Drugs

3

Description

Intervention group two: Bupivacaine and Epinephrine. 30 cc of 0.25% Bupivacaine and 1/200000 Epinephrine (in order to induce vasospasm and prolonging the time of drug in the tissue) will be infiltrated into the wound of the surgery after the operation is done.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital

Full name of responsible person

Mohammad Kamangar

Street address

Madani Sq. , Jahanshahr, Karaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Hatam Goodini

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Alborz 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

Alborz University of Medical Sciences

Full name of responsible person

Mohammad Kamangar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Position

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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