Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of topical effects of Bupivacaine, Epiphirin Bupivacaine and Bupivacaine-Dexamethasone on pain relief after lumbar disc surgery

Protocol summary

Study aim

Comparison of topical effect of Bupivacaine, Bupivacaine plus Epinephrine and Bupivacaine-Dexamethasone on pain relief after lumbar disc surgery Comparison of the effect of topical administration of Bupivacaine with controls on pain relief after lumbar disc surgery Comparison of the effect of topical administration of Bupivacaine-Epinephrine with control subjects on pain relief after lumbar disc surgery Comparison of the effect of topical use of Bupivacaine-Dexamethasone with control cases on pain relief after lumbar disc surgery

Design

This study is a clinical trial with control group, with 4 parallel groups each group of 10 samples (40 samples in total), double blind, randomized. In this study patients undergoing surgery are divided into four groups: one group of Bupivacaine topically one group of Bupivacaine plus epinephrine and another group of on-site Bupivacaine Dexamethasone. Surgical incision is used topically and in the control group there is no intervention.

Settings and conduct

This study is a double-blind clinical trial in which patients do not know the type of drug due to general anesthesia. Also, the team of researchers is not involved in the treatment process.

Participants/Inclusion and exclusion criteria

Over 20 and under 60 years, no uncontrolled underlying disease (ASA class 1 and 2), no history of drug abuse and drug abuse, patients requiring up to 4 spinal cord surgeries

Intervention groups

In this study patients undergoing surgery are divided into four groups: one group of bupivacaine topically one group of bupivacaine plus epinephrine and another group of bupivacaine dexamethasone at the site of surgical incision. The control group did not receive any intervention

Main outcome variables

Patients' pain at 3, 6, 12 and 24 hours after recovery based on Visual Anxiety Inventory (VAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200214046488N1**
Registration date: **2020-03-16, 1398/12/26**
Registration timing: **retrospective**

Last update: **2020-03-16, 1398/12/26**
Update count: **0**

Registration date

2020-03-16, 1398/12/26

Registrant information

Name

Mona Rastgar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5551 2520

Email address

m0na_rastegar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-16, 1398/06/25

Expected recruitment end date

2020-02-14, 1398/11/25

Actual recruitment start date

2019-09-16, 1398/06/25

Actual recruitment end date

2020-02-14, 1398/11/25

Trial completion date
2020-02-16, 1398/11/27

Scientific title
Comparison of topical effects of Bupivacaine, Epiphirin Bupivacaine and Bupivacaine-Dexamethasone on pain relief after lumbar disc surgery

Public title
Topical effect of Bupivacaine, Bupivacaine plus Epinephrine and Bupivacaine-Dexamethasone on pain relief after lumbar disc surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Ages 20 and under 60 years Absence of uncontrolled underlying disease (ASA Class 1 and 2) No history of drug abuse Patients who need up to 4 levels of the spine need surgery
Exclusion criteria:

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization was performed using the shuffling card method. In addition, measures have been taken by patients who were not directly involved in the study regarding patient registration, patient assignment, and patient management.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a double-blind clinical trial in which patients do not know the type of drug due to general anesthesia. Also, the team of researchers is not involved in the treatment process.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences
Street address
Ayatollah Musavi Hospital, Gavazang Road
City
Zanjan
Province
Zanjan
Postal code
4513956183

Approval date
2019-09-14, 1398/06/23

Ethics committee reference number
IR.ZUMS.REC.1398.219

Health conditions studied

1

Description of health condition studied
Lumbar Discopathy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Patient pain score based on VAS

Timepoint
3, 6, 12 and 24 hours after patient recovery

Method of measurement
Based on VAS (Visual Analog Scale)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: In this group, 20 mg Bupivacaine is added to the surgical incision site after surgery and before surgery, and then the incision site is closed.

Category
Treatment - Drugs

2

Description
Intervention group2: In this group, 20 mg Bupivacaine and 50 µg epinephrine were added to the surgical incision site before surgery and the incision site was closed.

Category

Treatment - Drugs

3

Description
Intervention group3: In this group, 20 mg Bupivacaine and 4 mg Dexamethasone will be added to the surgical incision site before surgery, and then the incision site will be closed.
Category
Treatment - Drugs

4

Description
Control group: In this group there is no intervention and no drugs are added
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Hospital
Full name of responsible person
Mona Rastegar
Street address
Gavazang Road
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Mousavihospital@zums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Alireza Shoghli
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Zanjan University of Medical Sciences, Islamic Republic Boulevard, Azadi Square
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shoghli@zums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Mona Rastgar
Position
Resident
Latest degree
Medical doctor
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Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not 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 questionnaires are fully shareable after ensuring that they are unrecognizable, including deleting the file name and number.
When the data will become available and for how long
Start access period 6 months after publishing results for 6 months
To whom data/document is available
The data will be available to all researchers at universities
Under which criteria data/document could be used
It is necessary for researchers to access the data to submit research proposals to academic institutions
From where data/document is obtainable
Contact Dr. Mona Rastegar and email m0na_rastegar@yahoo.com for data.
What processes are involved for a request to access data/document
The data becomes available to the researcher about 2 weeks after submitting the approved proposal to the academic institution.
Comments