

# 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

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

#### 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

#### 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, Epiphrin 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

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4513956183

##### Phone

+98 24 3313 0000

##### Email

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

##### Street address

Zanjan University of Medical Sciences, Islamic Republic Boulevard, Azadi Square

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4513956183

##### Phone

+98 24 3342 0651

#### Email

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

##### Other areas of specialty/work

Anesthesiology

##### Street address

Gavazang road

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4513956183

##### Phone

+98 24 3313 0000

##### Fax

##### Email

M0na\_rastegar@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Full name of responsible person

Mona Rastgar

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Anesthesiology

**Street address**

Gavazang road

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**Postal code**

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**Fax****Email**

M0na\_rastegar@yahoo.com

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

Zanjan University of Medical Sciences

**Full name of responsible person**

Mona Rastgar

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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**City**

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**Province**

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**Phone**

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**Fax****Email**

M0na\_rastegar@yahoo.com

**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**