

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The comparison of the effects of intraoperative injection of Methyl prednisolone, Morphine sulphate and Bupivacaine on patients' post-operative pain after lumbar discectomy

Protocol summary

Study aim

The effects of intraoperative injection of Methyl prednisolone, Morphine sulphate and Bupivacaine on patients' post-operative pain after lumbar discectomy

Design

This is a randomized clinical trial consisting of 5 groups including control group, one side blinded which will be performed on 150 patients at phase 3. The simple randomization method will be used individually for each patient.

Settings and conduct

This study will be performed in Imam Khomeini Hospital in Tehran and patients will receive medications at the end of surgery. Due to the fact that methylprednisolone has a special color, it is not possible for the physician to be blind the drug and the study will be one-sided blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients based on MRI diagnosed as intervertebral disc herniation (L4-L5 or L5-S1) who are candidates for open discectomy according to the attending physician's opinion. Exclusion criteria: patients aged below 18 and more than 65; addiction to opioids; known allergy to corticosteroids, morphins and bupivacaine; history of spine surgery.

Intervention groups

1- Patients who use 40 mg of methylprednisolone on their epidural space. 2- Patients who use 5 mg of morphine sulfate (soaked to a gelfoam) on their epidural space 3- Patients who receive 20 cc of bupivacaine as infiltrated into the paraspinal muscles and around the wound. 4- Patients who use 40 mg of methylprednisolone and 5 mg of morphine sulfate on the epidural space during surgery, and 20 cc bupivacaine are infiltrated into their paraspinal muscles and around the wound. 5- The control group in which gelfoam impregnated with normal saline is used in the epidural space and 20 cc of normal saline is infiltrated in the paraspinal muscles and around

the wound.

Main outcome variables

Pain after surgery; Number of needed intravenous opioids

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210815052193N1**

Registration date: **2022-05-02, 1401/02/12**

Registration timing: **prospective**

Last update: **2022-05-02, 1401/02/12**

Update count: **0**

Registration date

2022-05-02, 1401/02/12

Registrant information

Name

Mohamad Namvar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3262 5238

Email address

mohamad.namvar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of the effects of intraoperative injection of Methyl prednisolone, Morphine sulphate and Bupivacaine on patients' post-operative pain after lumbar discectomy

Public title
Effect of Methyl prednisolone, Morphine sulphate and Bupivacaine on post operation back pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients based on MRI diagnosed as intervertebral disc herniation (L4-L5 or L5-S1) who are candidates for open discectomy according to attending physician opinion
Exclusion criteria:
 patients aged below 18 and more than 65 Addiction to opioids known allergy to corticosteroids, morphins and bupivacaine History of spine surgery

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the simple randomization method will be used individually for each patient. we will put enough cards (as patients) named as groups numbers in an envelope. Each patient who is eligible to enter to the study will be assigned to a group by chance as each card comes out of the envelope.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, patients participating in the study will be blind about their group and the type of injected drugs. Due to the fact that one of the drugs has a special color, so it is not possible to keep the physician and researcher blind

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of the Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital, Baqer khan st

City

Tehran

Province

Tehran

Postal code

5651694774

Approval date

2021-10-09, 1400/07/17

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.236

Health conditions studied

1

Description of health condition studied

Low back pain after lumbar discectomy

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Severity of back pain after lumbar discectomy

Timepoint

At 3, 6, 12, 24 hours

Method of measurement

visual analogue score questionnaire

Secondary outcomes

1

Description

Number of needed intravenous opioids

Timepoint

24 hours after surgery

Method of measurement

Number of injected times by nurse

Intervention groups

1

Description

Intervention group: Patients who use 40 mg of methylprednisolone on their epidural space

Category

Treatment - Drugs

2

Description

Intervention group: Patients who use 5 mg of morphine sulfate (soakd to a gelfoam) on their epidural space

Category

Treatment - Drugs

3

Description

Intervention group: Patients who receive 20 cc of bupivacaine as infiltrated into the paraspinal muscles and around the woun

Category

Treatment - Drugs

4

Description

Intervention group: Patients who use 40 mg of methylprednisolone and 5 mg of morphine sulfate on the epidural space during surgery, and 20 cc bupivacaine are infiltrated into their paraspinal muscles and around the wound

Category

Treatment - Drugs

5

Description

Control group: The control group in which gelfoam impregnated with normal saline is used in the epidural space and 20 cc of normal saline is infiltrated in the paraspinal muscles and around the wound.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Mohamad Namvar

Street address

Imam Khomeini Hospital, Baqer khan St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Deputy of research

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Namvar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

Contact

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Data related to outcomes of the intervention would be shared

When the data will become available and for how long

1 year after publication of results

To whom data/document is available

Valid researchers

Under which criteria data/document could be used

for research purposes

From where data/document is obtainable

Mohamad Namvar

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

Email sending and assessing the request in ethics committee

Comments