Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

Study aim
The effects of intaoperative 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 (soakd 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)
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+98 45 3262 5238
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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 intaoperative 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 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 resuls
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