

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of Epidural injection of Methylprednisolon, Bupivacaine, and Normal saline on Management of Chronic Low back Pain due to lumbar Disc Herniation at a level

Protocol summary

Summary

Patients after signing written informed are randomly divided into three groups using statistical software. All patients initially admitted to the clinic after pain (see reference, direct or by specialist neurosurgery). Inclusion criteria: primary diagnosis of lumbar radicular pain due to discal hernia (bulging, protrusion) with MRI or CT_Scan result based evidences and age over 18 years old, starting with low back pain in 6 weeks. Exclusion criteria: for whom surgery is indicated; muscle weakness or numbness does not respond to progress or in electrodiagnostic be worse; urinary symptoms such as numbness and tingling or urine. Training will be required for the procedure and then randomly divided into three groups based on performance 28-person under lumbar epidural injection of methylprednisolone or bupivacaine or saline will be

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122625702N1**

Registration date: **2016-03-24, 1395/01/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-24, 1395/01/05

Registrant information

Name

Naghi Abeddini

Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-10-08, 1394/07/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Epidural injection of Methylprednisolon, Bupivacaine, and Normal saline on Management of Chronic Low back Pain due to lumbar Disc Herniation at a level

Public title

Lumbar epidural injections in chronic pain management

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with low back pain; does not respond to rest and medication, systemic therapy. Exclusion criteria: a history of cerebrovascular accidents and diseases; taking anti psychotic drugs; drug Abuse; patients with spinal stenosis; any bleeding areas prohibited for spinal anesthesia; unwillingness to participate in the study; indication for lumbar disc

surgery; the history of back pain due to disc herniation; ; low back pain due to Sacro iliac joint problems or rheumatic diseases.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 88

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golghasht Avenue

City

Tabriz

Postal code

Approval date

2015-04-27, 1394/02/07

Ethics committee reference number

TBZMED.REC.1394.703

Health conditions studied

1

Description of health condition studied

Chronic lumbar pain

ICD-10 code

M54.5

ICD-10 code description

Other obstetric conditions, not elsewhere classified

Primary outcomes

1

Description

Oswestry disability scale

Timepoint

The end of the first week, second, third, fourth and third month

Method of measurement

Questioning and examination

2

Description

Intensity of pain

Timepoint

The end of the first week, second, third, fourth and third month

Method of measurement

Observation and clinical examination

Secondary outcomes

1

Description

Bleeding

Timepoint

24 hours after intervention

Method of measurement

Clinical examination

2

Description

Dora tear

Timepoint

At the same time injection

Method of measurement

Observation at the time of injection

Intervention groups

1

Description

In the first group would be injected 80 mg of methylprednisolone Preparation of ten cc in volume into the epidural space of .

Category

Treatment - Drugs

2

Description

In the second group of local anesthetic bupivacaine 10 ml 0.5% into the epidural space

Category

Treatment - Drugs

3

Description

In the third group would be injected 10 ml of normal

saline solution into epidural space

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada hospital

Full name of responsible person

Dr. Naghi Abeddini

Street address

Shohada hospital, Parvaz St.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hasan Soleymanpour

Street address

Tabriz University of Medical Sciences

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty