Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of epidural injection of different volumes of Bupivacaine 0.5% combined with Methyl prednisolon in the management of low back pain due to disc herniation

Protocol summary

Summary

Aim is to determine the analgesic effectiveness of 10 and 15 ml of Caudal epidural Bupivacaine 0.5% with Mehtylprednisolone 80 mg injection for discogenic radicular pain control in one level. Method: In a single blinded, single center, randomized control trial with the help of "http://www.randomization.com/" website, seventy patients were included in two equal Intervention 1 and 2 groups at Imam Reza educational Hospital. Inclusion criteria: Patients with disc herniation in one level aged 30-70. Exclusion criteria: history of spinal surgery; canal stenosis; opiate abuse; psychotic disorders; history of allergic reactions to drugs and anatomical disorders in vertebral column. In order to define the effective volume and dose of local anesthetic, Intervention 1 group received 80mg Mehtylprednisolone (Manufactured by Caspian Tamin Darou Iran) in addition to 15ml 0.5%w/v Bupivacaine (75mg) Manufactured by Merck industries in France, from sacral hiatus into Caudal space by 18 Gage Tuohy needle, under fluoroscopy and contrast guidance. Intervention 2 group received 80mg Methylprednisolone in addition to 8ml 0.5%w/v Bupivacaine(40mg) in the same way. After recovery and discharge, Patients' pain score were assessed through the Visual Analogue Scale. Their Range of motion and the need for another block or other modality were recorded. This process would be assessed every month until 6 months and data would be recorded then analyzed and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201607111772N19**
Registration date: **2016-08-31, 1395/06/10**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-08-31, 1395/06/10

Registrant information

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Dawood Aghamohammadi
Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Faculty of Medicine,Tabriz University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of epidural injection of different volumes of Bupivacaine 0.5% combined with Methyl prednisolon in the management of low back pain due to disc herniation

Public title

Effectiveness of different volume of epidural local anesthetic for low back pain control

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patients with disc herniation in one level; aged 30-70. Exclusion criteria: canal stenosis; opiate abuse; psychotic disorders history of allergic reactions to drugs; anatomical disorders in vertebral column

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
By help of randomization site: http://www.randomization.com/

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
unite2, Vice Chancellor for Research, Fuculty of medicine, Tabriz University of Medical Sciences, Daneshghah street, Tabriz

City
Tabriz

Postal code

Approval date
2016-02-04, 1394/11/15

Ethics committee reference number
TBZMED.REC.1394.1010

Health conditions studied

1

Description of health condition studied
Sciatalgia

ICD-10 code
M51.1+

ICD-10 code description
Lumbar and other intervertebral disc disorders with radiculopathy (G55.1*) Sciatica due to intervertebral disc disorder

Primary outcomes

1

Description
Pain

Timepoint
every month until 6th month

Method of measurement
visual analog scale

Secondary outcomes

1

Description
Rang of Motion

Timepoint
every month until 6th month

Method of measurement
leg rise test

Intervention groups

1

Description
Intervention group 1: patients in this group received 80 mg Mehtylprednisolone (Manufactured by Caspian Tamin Darou Iran) plus 15ml 0.5%w/v Bupivacaine (75mg) Manufactured by Merck industries in France from sacral hiatus into Caudal space under fluoroscopy and contrast guidance by 18 Gage Tohy needle.

Category
Treatment - Drugs

2

Description
Intervention group 2: patients in this group received 80mg Methylprednisolone plus 8ml 0.5%w/v Bupivacaine (40mg) from sacral hiatus into Caudal space under fluoroscopy and contrast guidance by 18 Gage Tohy needle.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital/Tabriz

Full name of responsible person
Dawood Aghamohammadi

Street address
Imam Reza Hospital, Tabriz University of Medical Sciences, Daneshghah street, Tabriz

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Faculty of Medicine,Tabriz University of Medical Sciences

Full name of responsible person
Hassan Soleimanpour

Street address
Vice Chancellor for Research,Tabriz University of Medical Sciencest, Daneshghah Street, Tabriz

City
Tabriz

Grant name
-

Grant code / Reference number
-

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

Title of funding source
Vice Chancellor for Research, Faculty of Medicine,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
Anesthesiology Dept, Faculty of Medicine, Tabriz University of Medical Science

Full name of responsible person
Dawood Aghamohammadi

Position
Associate Professor

Other areas of specialty/work

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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