Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of epidural injection of glucocorticoid and glucocorticoid combined with bupivacaine in palliating chronic low back pain due to discopathy

Protocol summary

Summary

The objective of this randomized, double blind trial is to investigate the effect of epidural injection of glucocorticoid and glucocorticoid combined with bupivacaine in palliating chronic backache caused by discopathy. In this study, 40 patients with chronic backache who meet the inclusion/exclusion criteria will be recruited and randomly assigned into two groups. In one group, methyl prednisolone 80 mg will be administered via epidural injection. In the second group, in addition to methyl prednisolon 80 mg, bupivacaine 20 mg will also be blended and injected via epidural route in one syringe. Pain intensity, Oswestry disability index, and straight leg rising test will be measured at the baseline and 1 week, 2 weeks, 1 month to three month, and 6 months after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108137313N1**
Registration date: **2011-11-07, 1390/08/16**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-11-07, 1390/08/16

Registrant information

Name

Mirmohammadtaghi Mortazavi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3669 1953

Email address

mortazavimt@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of epidural injection of glucocorticoid and glucocorticoid combined with bupivacaine in palliating chronic low back pain due to discopathy

Public title

The effects of epidural injection of glucocorticoid and glucocorticoid combined with bupivacaine in palliating chronic low back pain due to discopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Chronic backache due to pure discogenic pain, signs of disk degeneration or herniation in MRI in the range of bulging to protrusion without motor and DTR involvement, Induction for epidural injection of glucocorticoid Exclusion criteria: Chronic backache less than 3 months, Previous surgery or the spinal column, Signs and symptoms of cauda equine,

canal stenosis and psychosomatic disorders, drug addiction, receiving any medical treatment

Age
No age limit

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **40**

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
Golgasht Ave., Tabriz , I.R.IRAN

City
Tabriz

Postal code
51665118

Approval date
2011-07-25, 1390/05/03

Ethics committee reference number
9038

Health conditions studied

1

Description of health condition studied
chronic low back pain

ICD-10 code
G54.4

ICD-10 code description
Nerve root and plexus compressions in intervertebral disc disorders

Primary outcomes

1

Description
pain severity

Timepoint
1 week, 2 weeks, 1 month to three months and 6 months

Method of measurement
pain free, mild, moderate, severe

2

Description
Straight leg rising test

Timepoint
1 week, 2 weeks, 1 month to three months and 6 months

Method of measurement
Posetive (less than 60 degrees) and negative (more than 60 degrees) and also clinical examination variables.

Secondary outcomes

1

Description
Return to normal activities, social and economic

Timepoint
1 week, 2 weeks, 1 month to three months and 6 months

Method of measurement
The question from patients

Intervention groups

1

Description
methyl prednisolone, 80 mg via epidural injection

Category
Treatment - Drugs

2

Description
methyl prednisolon, 80 mg, as well as bupivacaine 20 mg, injected via epidural route in one syringe

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Pain clinic of shohada hospital

Full name of responsible person
Dr. Mortazavi

Street address
Hospital shohada

City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
vice-chancellor for Research, Tabriz University of Medical Sciences
Full name of responsible person
DR.mortazavi
Street address
Shohada Hospital
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, 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
Reza Janmardi
Position
Assistant of anesthesia
Other areas of specialty/work
Street address
Tabriz University of Medical Sciences, Department of anesthesiology
City
Tabriz
Postal code
5165687386
Phone
+98 41 1286 8237
Fax
Email
Reza_janmardi@yahoo.cm
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shohada Hospital
Full name of responsible person
Dr. Mortazavi
Position
Assistant Professor
Other areas of specialty/work
Street address
Shohada Hospital
City
Tabriz
Postal code
51678846171
Phone
+98 41 1443 2150
Fax
Email
mortazavimt@yahoo.commortazavim@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
Position
Other areas of specialty/work
Street address
City
Postal code
Phone
+98 914 114 4266
Fax
Email
mortazavimmt@yahoo.com
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