

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 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 prednisolone 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