

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of the Effect of Epidural Corticosteroid Injection on Obese and Non-Obese Patients with Lumbar Disc Herniation

Protocol summary

Study aim

Comparison of the Effect of Epidural Corticosteroid Injection on Obese and Non-Obese Patients with Lumbar Disc Herniation

Design

Clinical trial without control group, 150 patients sample size, Trial phase 2-3

Settings and conduct

Tertiary regional and teaching hospital. Participants including major eligibility criteria, among the patients who were candidates for epidural steroid injection in the intralemnal method referred to the Akhtar Hospital in 2018, 150 were selected by Sequential method. Epidural injection of steroid is done by intralaminar method under fluoroscopic guidance at the pathology level. Main outcome measures (variables): Pain Level; disability.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients older than 18 years of age; Symptomatic Disc Hernia; Bilateral radiculopathy; Lumbar Disc disease; Patients with epidural injection Steroid. Exclusion criteria: Degenerative Disc Herniation; Presence of more than two herniated discs at different levels of lumbar; Local skin infections in the area of operation; Deformity of the Spine ; History of Lumbar Spine Surgery; Vertebral fracture; Tumor or Infection in the Spine; Inflammatory Spondylopathy; Neurological defects.

Intervention groups

Epidural steroid injection with 2 ml bupivacaine 2% and 6 ml distilled water and triamcinolone 40 mg / ml (total volume 8 ml)

Main outcome variables

Pain Level; disability.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131124015515N3**

Registration date: **2018-12-08, 1397/09/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-08, 1397/09/17**

Update count: **0**

Registration date

2018-12-08, 1397/09/17

Registrant information

Name

Masoud Hashemi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2261 2252

Email address

dr.hashemi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-30, 1397/09/09

Expected recruitment end date

2019-01-19, 1397/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Epidural Corticosteroid Injection on Obese and Non-Obese Patients with Lumbar Disc Herniation

Public title

Effect of Corticosteroid injection in Epidural Space in patients with Lumbar Disc Herniation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients older than 18 years Hernia disc and in case of stenosis of spinal cord involvement less than 30% based on clinical examinations and CT scan/MRI findings Symptomatic hernia, leg pain and unilateral radiculopathy Lumbar Disc Patients are candidates for epidural steroid injection Signed written informed consent to participate in the study

Exclusion criteria:

Body Mass Index <20 kg/m² Disc herniation at levels other than L4 to S1 Central hernia with extrusion pain or symptoms of progressive or severe sensory impairment More than two hernia discs at different levels of the lumbar History of steroid epidural injection in the last six months History of opioid abuse The latest use of long-acting opioids with radicular pain for more than a year Coagulation disorders, Steroid susceptibility, Malignancy Psychiatric problems and patient's lack of cooperation, speech problems Surgical indication, local skin infections in the area of operation, deformity of the spine and pregnancy History of lumbar spine surgery, cauda equina syndrome, vertebral fracture, tumor or infection in the spine, inflammatory spondylopathy, neurological defects

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Actual sample size reached: **124**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences and Health Services

Street address

Bone and Joint Diseases Research Center, Akhtar Hospital, Sharifi Manesh st.

City

Tehran

Province

Tehran

Postal code

1964714953

Approval date

2017-10-27, 1396/08/05

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.508

Health conditions studied**1****Description of health condition studied**

Hernia Disc Lumbar with radiculopathy

ICD-10 code

M51.16

ICD-10 code description

Intervertebral disc disorders with radiculopathy, lumbar region.

Primary outcomes**1****Description**

Pain Level

Timepoint

Before treatment, two, and six weeks after treatment

Method of measurement

visual analog scale (VAS) (0 None; 1-3 Mild; 4-7 Moderate; 8-10 Severe)

2**Description**

Disability Level

Timepoint

Before treatment, two, and six weeks after treatment

Method of measurement

Oswestry Low Back Disability Questionnaire that disability is measured with 10 items. Each item is scored from 5-0, which indicates a higher score for the disability.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Epidural steroid injection with 2 ml bupivacaine 2% and 6 ml distilled water and 40 mg / ml

triamcinolone (total volume 8 ml) in the target area.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar Hospital

Full name of responsible person

Seyed Masoud Hashemi MD

Street address

Pain Clinic, Akhtar Hospital, Sharifi Manesh st.

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+98 21 2260 8246

Email

dr.hashemi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi MD.

Street address

Shahid Arabi st., Yaman St., Shahid Chamran Expressway

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1985717443

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+98 21 2243 9781

Email

zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Masoud Hashemi MD.

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Akhtar Hospital, Sharifi Manesh st.

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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