Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 intraleminal method referred to the Akhtar Hospital in 2018, 150 were selected by Sequential method. Epidural injection of steroid is done by intralaminal 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.

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2261 2252

Fax

+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

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+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

Street address

Akhtar Hospital, Sharifi Manesh st.

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Email

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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