Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Fluoroscopy- guided intradiscal Radiopaque Gellified Ethanol injection using the anteroposterior view in comparison to oblique view – A Randomized Trial

Protocol summary

Study aim
The purpose of this study is to introduce the new technique of intradisc injection with anterior-posterior view and compare it with the traditional method which is performed obliquely.

Design
A controlled, parallel-group, double-blind, randomized clinical trial on 70 patients. A block of four was used for randomization.

Settings and conduct
All procedures and information are done and recorded in the operating room. The study is designed as a double-blind study, the analyst and the trained nurse who is recording the data are blind, so all procedures are performed by a professor.

Participants/Inclusion and exclusion criteria
The study includes patients who have given their consent to participate and are at least 18 years old. These individuals suffer from grade I and II herniated disc at L3 and/or L4, with spinal canal stenosis of less than 30% as determined by clinical examinations and MRI findings. They also experience chronic back pain for more than six months, symptomatic disc herniation, radial foot pain on one or both sides without any axial pain. Additionally, they should not have degenerative disc disease or a history of discogel injection in the last six months. Patients must not be using opioids or have any coagulation disorders. They should not be pregnant or have a history of malignancy or psychiatric problems. Furthermore, they should not have any spinal deformities, prior spine surgeries, traumatic injuries causing vertebral fractures, or infections in the vertebrae.

Intervention groups
In the intervention group, the anterior-posterior technique is used to guide the needle into the lumbar intervertebral disc.

Main outcome variables
In this study, the amount of radiation received by the patient and the duration of the procedure are recorded.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180603039966N3**
Registration date: **2023-12-03, 1402/09/12**
Registration timing: **prospective**

Last update: **2023-12-03, 1402/09/12**
Update count: **0**

Registration date
2023-12-03, 1402/09/12

Registrant information
Name
Sina Hasannasab
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-12-21, 1402/09/30
Expected recruitment end date
2024-03-18, 1402/12/28
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Fluoroscopy- guided intradiscal Radiopaque Gellified Ethanol injection using the anteroposterior view in comparison to oblique view – A Randomized Trial

Public title
New technique in intradiscal injection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
consent to participate individuals suffer from grade I and II herniated disc spinal canal stenosis of less than 30% as determined by clinical examinations and MRI findings chronic back pain for more than six months symptomatic disc herniation radial foot pain on one or both sides no axial pain do not have degenerative disc disease no history of RGE injection in the last six months no opioid usage no coagulation disorder not being pregnant no history of malignancy no history of spinal deformities, prior spine surgeries, traumatic injuries causing vertebral fractures, or infections in the vertebrae lumbar disc herniation in L3 and/or L4 no history of neurological impairments no history of psychiatric problems
Exclusion criteria:
Unexpected allergy to antiseptic agents Unexpected allergy to local anesthetics Unexpected allergy to intravenous sedatives
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants were randomized to treatment groups using a blocked randomization scheme with block sizes of 4, this means that participants were divided into blocks of four, and then each participant within a block was randomly assigned to one of the treatment groups. In this design, patients are randomly divided into 18 groups of four. Then, in each block that includes 4 patients, each injection technique is assigned equally among these four patients. In this way, each injection technique in each block is equally given to four subjects.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the person who is recording the time of the procedure and the exposure dosage is unaware of the technique used. For the person analyzing the information, the two groups are reported as groups A and B. Group A will be related to the Anterior-Posterior technique and Group B will be related to the Oblique technique.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid-Beheshti Medical University Ethics Committee
Street address
Shahid Chamran Highway - Yemen St. - Arabi St., Shahid Beheshti University of Medical Sciences and Healthcare Services - building number two of the university headquarters - 6th floor
City
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Province
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Postal code
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Approval date
2023-11-12, 1402/08/21
Ethics committee reference number
IR.SBMU.RETECH.REC.1402.454

Health conditions studied

1

Description of health condition studied
Intervertebral disc disorders with radiculopathy, lumbar region
ICD-10 code
M51.16
ICD-10 code description
Intervertebral disc disorders with radiculopathy, lumbar region

Primary outcomes

1

Description
radiation exposure
Timepoint
Is mesured during the application of intervention
Method of measurement
Dose area product (DAP) meters are utilized to evaluate

patient dose by employing an ionization chamber positioned on the collimator of the X-ray tube

2

Description
Procedure duration
Timepoint
The Procedure Time(PT) is carefully measured, beginning when the first fluoroscopic image was taken and ending only when the needle tip accurately reached its intended target point within the nucleus pulposus.
Method of measurement
chronometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In AP view technique, the entry point at which the needle penetrates, is measured through the use of a ruler feature in the MRI images software. In axial image, the line is drawn from center of the disc, passing the ateral border of superior articular process (SAP), to the surface of the skin, then the distance between the entry point and midline will be measured with the software. In AP technique, the desired injection level has been determined using an AP view with a C-Arm device. The procedure takes place under local anesthesia, with 1% lidocaine administered to numb the area. An 18 G Chiba needle is then inserted into the designated point at a distance of approximately 8-10 cm from midline(in accordance to MRI measurement), with 45 degrees angle, after penetration the needle is advanced into the skin until the tip of the needle ultimately hit against lower vertebrae's SAP. Then the needle will be walked off over the SAP, through the Kambine’s triangle. As we cautiously advance using stepwise movements until the tip of the needle passes medial border of the SAP in AP view, the C-Arm device will be rotated for a true lateral view to control the depth of the needle, we will advanced the needle until hitting resistance, and penetrated through the disc. The needle will be andvanced until the tip is center of the intervertebral disc.
Category
Treatment - Other

2

Description
Control group: In the oblique technique, in order to ascertain precise accuracy throughout this process, every patient's injection site anatomy as well as the needle's trajectory path are determined through guidance provided by C-arm imaging. Once these factors have been meticulously identified, we proceed by squering involved vertebrae, then utilizing an oblique view. Within this viewpoint, we carefully select an appropriate point on the skin for needle insertion before delicately introducing an Chiba 18G needle into target disc. As soon as we reach beyond the medial border of the pedicle in anteroposterior (AP) view, confirmation is sought via lateral view analysis. Upon receiving confirmation through this holistic assessment approach and having successfully located our target within center of the intervertebral disc further advancement ceases accordingly at that particular point of penetration with regards to needle tip placement.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Medical & Educational Center
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Sponsors / Funding sources

1

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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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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