Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Epidural Needle Placement and Reliability in Interlaminar Epidural Steroid İnjection in the Cervical Region with the Hanging Drop and Loss of Resistance Methods Accompanied by Fluoroscopy in the Prone Position - Prospective Randomized Controlled Clinical Study

Protocol summary

Study aim

The two most commonly used techniques for epidural injection are loss of resistance (LOR) and hanging drop (HD) techniques. Hoffman et al. Determined that the LOR technique in the lateral position has a lower dural risk compared to HD. In the meta-analysis study conducted by Ludmil Todorov et al., It was stated that the HD technique can be preferred in the sitting position because the intrinsic negative pressure is more obvious in the cervical and thoracic epidural area, and there is no evidence regarding the advantage of the HD technique over the LOR in the lumbar area. No study was found in the literature examining the epidural placement and reliability of the needle in the Interlaminar Epidural Steroid Injection applied in the cervical region with the hanging drop and loss of resistance techniques under fluoroscopy in the prone position. In this study, we aimed to investigate which technique is more suitable for determining the epidural area with contrast material under fluoroscopy.

Design

Single center, a prospective, observational

Settings and conduct

The patients dont know which technique to apply

Participants/Inclusion and exclusion criteria

Inclusion criteria - Cervical disc herniation Exclusion criteria - Patients who have had surgery in the cervical region

Intervention groups

After the patients are laid face down and the neck area is sterilized, the area to be entered is numbed with local anesthesia, then an epidural steroid injection is made to this area using the Hanging Drop or Lost of resistance method under fluoroscopy.

Main outcome variables

1. Which technique is more reliable? 2. What are the possible complications?

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240503061634N1**
Registration date: **2024-09-23, 1403/07/02**
Registration timing: **registered_while_recruiting**

Last update: **2024-09-23, 1403/07/02**
Update count: **0**

Registration date

2024-09-23, 1403/07/02

Registrant information

Name
Shahin Azizov
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-08, 1403/03/19

Expected recruitment end date

2024-09-30, 1403/07/09

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Epidural Needle Placement and Reliability in Interlaminar Epidural Steroid İnjection in the Cervical Region with the Hanging Drop and Loss of Resistance Methods Accompanied by Fluoroscopy in the Prone Position - Prospective Randomized Controlled Clinical Study

Public title
Cervical Epidural İnjection

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
cervical disc herniation
Exclusion criteria:
Operated cervical disc herniation

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be provided as follows. Patients will be processed consecutively, one with the LOR method and the other with the HD method. The number of patients to be included will be determined at the study time by performing a power analysis.

Blinding (investigator's opinion)
Single blinded

Blinding description
The patient does not know which method will be used

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Azerbaijan Medical University

Street address
9RWM+64M Samad Vurgun

City
Baku

Postal code
1022

Approval date
2024-06-07, 1403/03/18

Ethics committee reference number
33

Health conditions studied

1

Description of health condition studied
cervical disc displacement

ICD-10 code
M50.20

ICD-10 code description
Other cervical disc displacement, unspecified cervical region

Primary outcomes

1

Description
Whether the tip of the needle is in the epidural area

Timepoint
At the time of the procedure and after 3 weeks

Method of measurement
Will be evaluated by spreading the contrast over the required area

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Steroid injection will be made into the cervical epidural area with the LOR technique. If the contrast given without pressure loss is in the epidural space, it is considered unsuccessful, and if the contrast given despite pressure loss is not in the epidural space, or even if it is suspicious epidural, it is considered unsuccessful. If there is a pressure loss, if the contrast given is in the epidural space, the procedure will be considered successful. Post-procedure complications will also be examined. Intervention group2: Steroid injection will be made into the cervical epidural space with the HD technique. If the fluid in the Hub part of the needle falls with negative pressure in the HD technique and we see the given contrast in the epidural area with fluoroscopy, the procedure will be considered successful. If the contrast spreads into the epidural space without falling

or if the contrast does not spread into the epidural space while falling or if it is suspicious epidural, the procedure will be considered unsuccessful.Post-procedure complications will also be examined.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

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Web page address
https://agrihekimi.az/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Ege
Proportion provided by this source
1
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
Comparison of Epidural Needle Placement and Reliability in Interlaminar Epidural Steroid İnjection in the Cervical Region with the Hanging Drop and Loss of Resistance Methods Accompanied by Fluoroscopy in the Prone Position - Prospective Randomized Controlled Clinical Study

When the data will become available and for how long
Made available (starting 3 months after publication)

To whom data/document is available
This only available for people working in academic institutions

Under which criteria data/document could be used
Prospective Randomized Controlled Clinical Study

From where data/document is obtainable
shahinazizov1@gmail.com

What processes are involved for a request to access data/document
The data will be officially available after sending a message to the e-mail

Comments
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