

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Epidural Needle Placement and Reliability in Interlaminar Epidural Steroid Injection 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

Name of organization / entity

EGE hospital

Country

Azerbaijan

Phone

+994 51 435 79 75

Email address

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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 Injection 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 Injection

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**

Ege hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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****Name of organization / entity**

Ege

Full name of responsible person

Sahin Azizov

Position

Fellow MD

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Person responsible for updating data

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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 Injection 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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