

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Comparison between two steroid administration methods into the epidural space (Trans-formalin and inter laminar) on drug volume distribution to the anterior epidural space in patients with chronic radicular pain

Protocol summary

Study aim

Comparison of the contrast agent diffusion into frontal epidural with two TF and PE approaches in patients referred to Imam Khomeini Hospital's pain clinic with chronic pain at 1397.

Design

Two arm parallel groups randomized trial with blinded postoperative care and outcome assessment

Settings and conduct

Sixty patients admitted to Imam Khomeini Hospital's pain clinic with history of lumbar spine pain, included in the study according to the inclusion and exclusion criteria. After that the subjects separated into two TF and PE groups based on block randomization with randomly selected block sizes of 4.

Participants/Inclusion and exclusion criteria

35 to 75 years old patients suffered from disc Extrusion, disc Protrusion and disc degeneration with at least 50 % preserved intervertebral disc height included in the study. Exclusion criteria were patients underwent spinal surgery, patients with history of lumbar epidural steroid injection (LESI), Patients with diabetic nephropathy and patients with serum creatinine level less than 2mg/dl.

Intervention groups

group PE: The epidural needle- B. Braun (10 cm Tuohy-type-17G) will be introduced at the level of damaged disc with the technique of loss of resistance and inclined to the lesion. After the needle enters the epidural space, 5 ml omnipaque 240 will be injected then anteroposterior (AP) and lateral fluoroscopy images will be taken. Finally, the mixture of 40 mg prednisolone, 4 ml normal saline and 5 ml lidocaine 2% will be injected into the epidural space. group TF: curved blunt RF-needle (15 cm) will be introduced into desired foramen and under the pedicul. Then local anesthetic agent will be injected following the injection of 5 ml contrast agent.

Main outcome variables

Distribution of drug contrast to the anterior epidural space

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200209046437N1**

Registration date: **2020-04-23, 1399/02/04**

Registration timing: **retrospective**

Last update: **2020-04-23, 1399/02/04**

Update count: **0**

Registration date

2020-04-23, 1399/02/04

Registrant information

Name

Narges Khojasteh Kalansara

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-02, 1398/05/11

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

2019-08-08, 1398/05/17

Actual recruitment end date

2019-08-30, 1398/06/08

Trial completion date

2020-03-04, 1398/12/14

Scientific title

Comparison between two steroid administration methods into the epidural space (Trans-formalin and inter laminar) on drug volume distribution to the anterior epidural space in patients with chronic radicular pain

Public title

Evaluation of two steroid injection methods on drug distribution

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with Herniated Disk with at least 50% remained height of the inter-vertebral disc.

Exclusion criteria:

previous spine surgery record Epidural lumbar spine steroid injection in the last years

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomize allocation Patients will be randomly introduce to the two determined groups : trans-formalin and parasitital inter-laminar. randomize allocation method for the two groups is block randomization, as lo block size has been considered 6 persons. And the patient assignment sequences will be determined to the groups by Random allocation software, , and this sequence will be kept by the project manager. None of the participants in this study will be aware of the randomization method also in order to conceal the randomization process, color folders with sequentially specific number will be used , These folders will be held by the project manager who is aware of the assigned treatment groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are not aware about that they are going to be assigned in which study group .The doctor who performs the block is different from the doctor who reviews the

outcome of the study. So the physicians who study the outcome are not aware of the patients in the study groups. It is important to say that distribution of Radio contrast agent into the epidural space will be done by fluoroscopic examination in a completely different session from the radiologist's block. Clinical outcomes of the study (pain severity reduction and life quality changes) will also be performed by another anesthesiologist (assistant) in a different session from the block session in the clinic or by telephone follow-up.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

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No 226, Central organization, Ghods Street, Keshavarz Boulva

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Postal code

1417653761

Approval date

2019-03-13, 1397/12/22

Ethics committee reference number

IR.TUMS.IKHC.REC.1397.359

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

Waist disc

ICD-10 code

M51.16

ICD-10 code description

Intervertebral disc disorders with radiculopathy, lumbar region

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

Contrast distribution pattern

Timepoint

During the intervention

Method of measurement
Fluoroscopic photographs

Secondary outcomes

1

Description
pain

Timepoint

Before the intervention - two weeks, 1 month 3 month and 6 months after the intervention

Method of measurement
11-point numeric scale

2

Description
Change of quality of life

Timepoint

Before intervention , 2 weeks after intervention , 1 months after intervention , 3 months after intervention, 6 months after intervention

Method of measurement
SF36 Questionnaire

Intervention groups

1

Description
Intervention group: Epidural needle G 10 cm Tuohy-type-17 B-brown is placed on the surface of the damaged disc with loss of resistance technique and inclined to the lesion. After the needle was inserted into the omnipaque 240, 5 ml and then a mixture of 40 mg of prednisolone, 4 ml of normal saline and 5 ml of 2% lidocaine were injected into the epidural space.

Category
Treatment - Drugs

2

Description
Control group : The RF Needle, 15cm, blunt, curved needle will be inserted into the foramen under the pedicle. Then 5 ml of contrast is injected and then the combination of steroids and local anesthetic is injected.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini hospital

Full name of responsible person
Narges Khojasteh Kalansra

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Imam Khomeini Hospital Complex, Gharib Street , end

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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?

Yes

Title of funding source

Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Narges Khojasteh Kalansra

Position
Residency

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected deidentified IPD can be shared

When the data will become available and for how long

6 months after publication

To whom data/document is availablePeople working in academic institutions and people
working in businesses**Under which criteria data/document could be used**

Planning of similar studies in other academic centers

From where data/document is obtainable

Email address

What processes are involved for a request to access data/document

After request during the 1-2 months

Comments