Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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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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 parasitical 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
Street address
No 226, Central organization, Ghods Street, Keshavarz Boulva
City
Tehran
Province
Tehran
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
Street address
Imam Khomeini Hospital Complex, Gharib Street , end of keshavarz Blvd
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Sponsors / Funding sources

1

Sponsor
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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
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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 available
People 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