Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the pain in transforaminal epidural steroid injections and pulsed radiofrequency in patients with low back pain

Protocol summary

Summary

Objectives: This study is aimed to compare the pain in transforaminal epidural steroid injections and pulsed radiofrequency in patients with chronic radicular low back pain who were referred to Rasul Hospital between 2013-2015 years. Design: Randomized clinical trial Setting and conduct : Tertiary regional and teaching hospital. Participants including major eligibility criteria: Forthy two Patients with chronic radicular low back pain who were referred to Rasul Hospital between 2013-2015 years, were included . Patients were randomized into two groups of 21 each, using a table of random numbers. Interventions: control group , patients received, epidural steroid injection method transforaminal interlaminar under fluoroscopic guidance close to the site of the pathology . Study group , patients received, pulsed radiofrequency in the nerve segment is confirmed with a positive diagnostic block. Main outcome measures (variables): Visual analog scale; Oswestry disability index score; Success rate; Patient request for analgesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411037984N22**
Registration date: **2015-04-06, 1394/01/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-04-06, 1394/01/17

Registrant information

Name

Farnad Imani

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6651 5758

Email address

farnadimani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences and Health Services

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2015-02-17, 1393/11/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the pain in transforaminal epidural steroid injections and pulsed radiofrequency in patients with low back pain

Public title

Comparison decrease of the pain in transforaminal epidural steroid injections and pulsed radiofrequency in patients with low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Main inclusion criteria: Persistent low back pain with or without pain radiating to the upper leg; Age > 18 years old; ASA Class I- II; Lasek test =>50 degrees; Confirming the involvement of nerve roots , vertebral disc protrusion is based on clinical examination and CT scan and MRI

findings; Symptoms of chronic low back pain for more than six months; Absence of neurological defects; Absence of epidural injection; Absence of radicular syndrome; No respond to traditional treatments; Positive diagnostic block; Hyperextension pain; No history of lumbar surgery; Contraindication of lumbar surgery; Signing consent to participate in the study. Main exclusion criteria: Patients previously treated with radiofrequency; Coagulation disorders; Contrast sensitivity radio- opaque or local anesthetic solution; Malignancy; Psychiatric problems and poor patient cooperation; Speech problems; Pregnancy; Surgery indication; Local skin infection at the operative site; Spinal deformities; Spinal stenosis; Discogenic axial pain; Degenerative disc herniation; Epidural injection of steroids in the past six months; History of opioid abuse; Use of long -acting opioids recent Radicular pain over a year ago; Patients with a history of sensitivity to corticosteroids or contrast material; Inflammatory spondylopathy; Vertebral fracture , tumor , or infection of the spine; No signing consent to participate in the study.

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

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 and Health Services

Street address
Poursina St.

City
Tehran

Postal code

Approval date
2013-08-21, 1392/05/30

Ethics committee reference number
130/1077/92

Health conditions studied

1

Description of health condition studied
Low back pain

ICD-10 code
M54.5

ICD-10 code description
Low back pain

Primary outcomes

1

Description
Pain score

Timepoint
Before the treatment, 24 hours, 1 week, 1 month, 3 months after the treatment

Method of measurement
Visual analog scale

2

Description
Disability measurement

Timepoint
Before the treatment, 24 hours, 1 week, 1 month, 3 months after the treatment

Method of measurement
Oswestry disability index score

3

Description
Successful treatment rate

Timepoint
3 months after the treatment

Method of measurement
Pain relief more than 50%

4

Description
Patient request for analgesia

Timepoint
Before the treatment, 24 hours, 1 week, 1 month, 3 months after the treatment

Method of measurement
Based on the patient's request

Secondary outcomes

empty

Intervention groups

1

Description
In the study group, Pulsed radiofrequency
Category
Rehabilitation

2

Description
In the control group, Transforaminal epidural steroid injection
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasul Hospital
Full name of responsible person
Farnad Imani MD.
Street address
Satarkhan St.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences and Health Services
Full name of responsible person
Shahin Akhunzadeh MD.
Street address
Poursina St.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tehran University of Medical Sciences and Health Services
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Rasul Hospital
Full name of responsible person
Farnad Imani MD.
Position
Associate professor
Other areas of specialty/work
Street address
Satarkhan St.
City
Tehran
Postal code
Phone
+98 21 6435 2326
Fax
Email
farimani@tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasul Hospital
Full name of responsible person
Farnad Imani MD.
Position
Associate professor
Other areas of specialty/work
Street address
Satarkhan St.
City
Tehran
Postal code
Phone
+98 21 6435 2326
Fax
Email
farimani@tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Rasul Hospital
Full name of responsible person
Farnad Imani MD.
Position
Associate professor
Other areas of specialty/work
Street address
Satarkhan St.
City
Tehran
Postal code
Phone
+98 21 6435 2326

Fax

Email

farimani@tums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty