

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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: Forty 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