

# 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

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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## Person responsible for updating data

### Contact

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**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*