

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### A comparison of the effects and complications of transforaminal Triamcinolone and Dexmedetomidine in radicular low back pain.

#### Protocol summary

##### Summary

Objectives: Chronic radicular Low Back Pain is One of The Most Common Cause of Pain Clinic Admission Which is treated with Epidural Transforaminal Steroid Injection. Due to Steroid Injection Side Effects, We Decided to Compare Dexmedetomidine Effect in This Study. Study design (study participation - sample size), Exclusion and inclusion criteria: Sample size is 30 patients. Patients with chronic low back pain which fulfill study criteria, randomly assigned into two groups by block randomization. The study will be done double - blinded. Intervention: Patients under local anesthesia and fluoroscopic guidance in operative room, transforaminal epidural block will be done. In group 1, Ropivacaine 0.2%, 3cc with Triamcinolone 20 mg and in group 2, Ropivacaine 0.2% ,3cc with Dexmedetomidine 1 microgram per kilogram will be injected. Visual analog scale, ODI, analgesic need, SLR (straight leg raise) will be checked as follow: before injection, 2 weeks later first, 3 and 6 month later. FBS will be checked and Recorded as follow: before injection, 2 weeks later and first month later. Ca, Mg, Vit.C and Vit.D will be checked and Recorded as follow: before and 1 month later. The results will be analyzed and compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201312037984N12**  
Registration date: **2017-09-15, 1396/06/24**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-09-15, 1396/06/24

#### 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 and Technology of Iran  
University of Medical Sciences

#### Expected recruitment start date

2017-09-23, 1396/07/01

#### Expected recruitment end date

2018-06-22, 1397/04/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A comparison of the effects and complications of transforaminal Triamcinolone and Dexmedetomidine in radicular low back pain.

#### Public title

A comparison of the effects and complications of transforaminal Triamcinolone and Dexmedetomidine in radicular low back pain.

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria Age 20-70 years; Pain that has not

responded to treatment for at least 6 weeks; Evidence of Nerve root involvement as disc bulging and/or foraminal stenosis in CT/MRI; VAS > 4; ASA class I, II; Patients' Informed consent Exclusion criteria: Patients with coagulopathy ; Infection in injection site as Herpetic diseases; Anatomical and congenital spine deformity as severe scoliosis; Surgical history instrument insertion; Psychological severe disorders; History of harmful reaction to local anesthetic and steroid; Patients with motor deficit or progressive neural defect; Cancer ; Neural foramen radiological access difficulty; Substance abuse; HIV; Acute trauma; Cauda Equina syndrome; More than 3 level abnormalities ;. Absence of radicular pain

#### **Age**

From **20 years** old to **70 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **30**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

This study is double blinded. Patients and evaluators had no information about drug of injection.

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Iran University of Medical Sciences.

###### **Street address**

Iran university of medical science, Hemmat highway, Tehran

###### **City**

Tehran

###### **Postal code**

1445613131

###### **Approval date**

2017-05-22, 1396/03/01

###### **Ethics committee reference number**

IR.IUMS.FMD.REC 1396.30894

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

chronic low back pain

##### **ICD-10 code**

G54.8

##### **ICD-10 code description**

low back pain

### **Primary outcomes**

#### **1**

##### **Description**

low back pain

##### **Timepoint**

Before injection, two weeks, 1, 3 and 6 month after intervention

##### **Method of measurement**

pain score measured with visual analogue scale in Questionnaire.

### **Secondary outcomes**

#### **1**

##### **Description**

Oswestry Disability Index questionnaire (ODI) and straight leg raising test (SLR), complications

##### **Timepoint**

Before injection, two weeks, 1, 3 and 6 month after intervention.

##### **Method of measurement**

Questionnaire

### **Intervention groups**

#### **1**

##### **Description**

In intervention group 3 ml 0.2% Ropivacaine (Ropivacaina Molteni, Molteni, Italy) plus Dexmedetomidine 1 microgram per Kilogram (Precedex, Hospira, USA) was injected in the selected level by a curved blunt tip 10 cm needle (Cosman, USA) under fluoroscopic guidance via transforaminal epidural approach.

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

In control group 3 ml 0.2% Ropivacaine (Ropivacaina Molteni, Molteni, Italy) plus 20 mg Triamcinolone (Triamcinolone acetate, EXIR, IRAN) was injected in the selected level by a curved blunt tip 10 cm needle (Cosman, USA) under fluoroscopic guidance via transforaminal epidural approach.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rasool Akram Medical Center

**Full name of responsible person**

Dr Farnad Imani

**Street address**

Pain Research Center, Department of Anesthesiology and Pain Medicine, Rasool Akram Medical Center, Niayesh St. Sattar Khan St

**City**

tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for Research and Technology of Iran University of Medical Sciences

**Full name of responsible person**

Dr Seyyed Ali Javad Mousavi

**Street address**

Hemmat Expressway, Iran University of Medical Sciences

**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 and Technology of Iran University of Medical Sciences

**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**

Rasool Akram Medical Center

**Full name of responsible person**

Dr Farnad Imani

**Position**

Interventional pain fellowship, professor of anesthesiology

**Other areas of specialty/work****Street address**

Pain Research Center, Department of Anesthesiology and Pain Medicine, Rasool Akram Medical Center, Niayesh St. Sattar Khan St

**City**

tehran

**Postal code**

1445613131

**Phone**

+98 21 6651 5758

**Fax**

+98 21 6651 5758

**Email**

farnadimani@yahoo.com

**Web page address**

www.anesthpain.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Science

**Full name of responsible person**

Dr. Farnad Imani

**Position**

professor of anesthesiology, Interventional pain fellowship

**Other areas of specialty/work****Street address**

Pain Research Center, Department of Anesthesiology and Pain Medicine, Rasool Akram Medical Center, Niayesh St. Sattar Khan St

**City**

tehran

**Postal code**

1445613131

**Phone**

+98 21 6651 5758

**Fax**

+98 21 6651 5758

**Email**

farnadimani@yahoo.com

**Web page address**

www.anesthpain.com

**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Science

**Full name of responsible person**

Dr. Poupak Rahimzadeh

**Position**

Anesthesiologist, Interventional pain fellowship, Associated professor of anesthesiology

**Other areas of specialty/work****Street address**

Pain Research Center, Department of Anesthesiology

and Pain Medicine, Rasool Akram Medical Center,  
Niayesh St. Sattar Khan St

**City**

tehran

**Postal code**

1445613131

**Phone**

+98 21 6651 5758

**Fax**

+98 21 6651 5758

**Email**

poupak\_rah@hotmail.com

**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*