

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Ultrasound-guided vs. fluoroscopic-guided epidural steroid injection in lower lumbar radicular pain: a prospective, randomized, single-blind clinical trial.

#### Protocol summary

##### Summary

The present single blind randomized clinical trial is designed to evaluate the feasibility of ultrasound guided epidural steroid injection and compare the effects with standard fluoroscopic technique in patients presented with lower lumbar radicular pain. 30 patients aged between 15-70 years who meet the inclusion criteria recruited in the study. the patients are randomly divided in two groups of 15, each group is assigned each technique. under proper position, a Tuohy epidural needle G-18 is inserted and after negative aspiration, 1-2 ml of contrast agent is injected. contrast distribution pattern is evaluated regarding filling the epidural space. Injection duration and adverse effects (if any) are recorded in patients' profiles. all the patients are re-evaluated 48 hrs and two weeks after the intervention. to assure blindness, evaluation of all radiologic images and also patients' examinations are done by a colleague, blind to the injection technique.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016091629832N1**

Registration date: **2017-05-13, 1396/02/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-05-13, 1396/02/23

##### Registrant information

##### Name

SeyedMohammadReza Hajiseyedaboutorabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2291 2252

##### Email address

aalaei@alumnus.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2016-10-22, 1395/08/01

##### Expected recruitment end date

2017-01-20, 1395/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Ultrasound-guided vs. fluoroscopic-guided epidural steroid injection in lower lumbar radicular pain: a prospective, randomized, single-blind clinical trial.

##### Public title

comparison of two technique of sonography and fluoroscopy in epidural steroid injection for lumbar back pain

##### Purpose

Other

##### Inclusion/Exclusion criteria

inclusion criteria: age between 15-70 years; diagnosis of intervertebral disc herniation or canal stenosis confirmed by clinical history & examination, EMG, CT or MRI tests.  
exclusion criteria: systemic inflammatory diseases; being under treatment by anti-coagulants; need to consume

NSAIDs; uncontrolled diabetes; history of allergic reaction to contrast agents; history of injection or surgery during past 3 months; infection; skin defect in injection site; psychotic problems.

#### **Age**

From **15 years** old to **70 years** old

#### **Gender**

Both

#### **Phase**

N/A

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

*No information*

#### **Sample size**

Target sample size: **30**

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

Randomized

#### **Randomization description**

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

Single 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 Shahid Beheshti University of Medical Sciences

##### **Street address**

Next to Taleghani Hospital, Arabi Ave. Yaman St. Chamran Exp.

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2017-03-05, 1395/12/15

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

IR.SBMU.RETECH.REC.1395.1012

## **Health conditions studied**

### 1

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

Radicular lumbar pain

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

M54.1

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

Radiculopathy

## **Primary outcomes**

### 1

#### **Description**

contrast distribution pattern

#### **Timepoint**

during the intervention

#### **Method of measurement**

compatible/ non-compatible with the research standard protocol

## **Secondary outcomes**

### 1

#### **Description**

pain

#### **Timepoint**

Before the intervention - 48 hrs and two weeks after the intervention

#### **Method of measurement**

0-10 based on VAS

### 2

#### **Description**

Function

#### **Timepoint**

Before the intervention - 48 hrs and two weeks after the intervention

#### **Method of measurement**

0-100 based on ODI

### 3

#### **Description**

patients satisfaction

#### **Timepoint**

48 hrs and two weeks after the intervention

#### **Method of measurement**

0-5 based on PSQ

### 4

#### **Description**

adverse effects

#### **Timepoint**

During the intervention - 48 hrs and two weeks after the intervention

#### **Method of measurement**

examination

### 5

#### **Description**

duration of the injection

#### **Timepoint**

During the intervention

#### **Method of measurement**

based on seconds using cronometer

## Intervention groups

### 1

#### Description

intervention group: epidural injection of 8ml triamcinolone, 2ml marcaine .05% and 1 ml non-ionic contrast agent under the guide of ultrasound

#### Category

Treatment - Other

### 2

#### Description

Control group: epidural injection of 8ml triamcinolone, 2ml marcaine .05% and 1 ml non-ionic contrast agent under the guide of flouroscope

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Akhtar Hospital

##### Full name of responsible person

Dr. Alireza Glinimoghadam

##### Street address

##### City

Tehran

### 2

#### Recruitment center

##### Name of recruitment center

Imam-Hosseini Hospital

##### Full name of responsible person

Dr. Alireza Glinimoghadam

##### Street address

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice president of research, Shahid Beheshti University of Medical Sciences, Dr.Ziaee

##### Full name of responsible person

Sayed-masoud Hashemi

##### Street address

3rd floor, Medical School, Next to Taleghani Hospital, Evin, Chamran Exp.

##### City

Tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor

#### organization/entity?

Yes

#### Title of funding source

Vice president of research, Shahid Beheshti University of Medical Sciences, Dr.Ziaee

#### 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Alireza Glini-moghaddam

##### Position

Pain Fellowship resident

##### Other areas of specialty/work

##### Street address

Pain Clinic, Akhtra Hospital, Elahie

##### City

Tehran

##### Postal code

##### Phone

+98 21 2261 2252

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##### Email

homeopathylover@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Sayed-Masoud Hashemi

##### Position

Associated Prof.

##### Other areas of specialty/work

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##### Web page address

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Alireza Glini-moghadam

**Position**

Pain Fellowship resident

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

Tehran, Elahie

**City**

Tehran

**Postal code****Phone**

+98 912 031 2927

**Fax****Email**

## 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*