Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 nin 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

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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 committe 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 basedon 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 injetion

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-Hossein Hospital
Full name of responsible person
Dr. Alireza Glinimoghadam
Street address
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice president of research, Shahid Behehsti University of Medical Sciences, Dr.Ziaee
Full name of responsible person
Seyed-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 Behehsti 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
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Person responsible for updating data

Contact

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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