

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

a survey on sonographic guided transforaminal injection on pain among patients with lumbar radiculopathy

Protocol summary

Study aim

to detect the effect of sonographic guided transforaminal lumbar injection on pain in patients with lumbar radiculopathy

Design

a clinical trial without randomization on 30 patients with lumbar radiculopathy

Settings and conduct

this study was done in shahid behesti hospital, babol city. the ultrasound guided transforaminal injection is done and the level and the situation of needle was controlled with fluoroscopy after injection of radiopaque agent and documented, at that time the corticosteroid (triamcinolone) was injected. Also pain score for patients was documented in 1st, 3rd and 7th days and also first and 3rd months after injection.

Participants/Inclusion and exclusion criteria

Inclusion: low back pain or radicular pain with evidence of pressure and stenosis of the nerve root canal displayed in a recent MRI exclusion: contraindication for epidural injection, overweight (30 < BMI), have had previous epidural injection, non-stable neurological problems like Cauda equina syndrome and also patients who did not cooperate in the investigation

Intervention groups

On prone position, with the curve of ultrasound transducer on the parasagittal oblique position, with out-of-plane technique a peripheral venous catheter (# 16) was advanced to the lamina, then the transducer position was changed to axial position and an Epidural catheter was placed about 8 Cm from midline and advanced under sonography guide with the in plane technique to the intervertebral foramen. The level and the situation of needle was controlled with fluoroscopy the corticosteroid (triamcinolone) was injected. Also pain score for patients was documented in 1st, 3rd and 7th days and also first and 3rd months after injection.

Main outcome variables

pain score based on visual assessment score (VAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200805048309N1**

Registration date: **2020-08-16, 1399/05/26**

Registration timing: **retrospective**

Last update: **2020-08-16, 1399/05/26**

Update count: **0**

Registration date

2020-08-16, 1399/05/26

Registrant information

Name

behnam baghianimoghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3225 4392

Email address

b.baghianimoghadam@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

2017-07-11, 1396/04/20

Actual recruitment end date

2017-07-11, 1396/04/20

Trial completion date

2017-07-11, 1396/04/20

Scientific title

a survey on sonographic guided transforaminal injection on pain among patients with lumbar radiculopathy

Public title

sonographic guided transforaminal lumbar injection on pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

low back pain and also radicular pain of one or both lower extremities evidence of pressure and stenosis of the nerve root canal in one or more levels displayed in a recent MRI which was not alleviated by initial conservative treatment

Exclusion criteria:

contraindication for epidural injection overweight (30 <BMI) previous epidural injection non-stable neurological problems not cooperate in the investigation

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Actual sample size reached: 30

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical sciences

Street address

Ganjafrooz street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

4717647754

Approval date

2016-10-18, 1395/07/27

Ethics committee reference number

9542923

Health conditions studied

1

Description of health condition studied

radicular low back pain

ICD-10 code

M48.0

ICD-10 code description

Spinal stenosis

Primary outcomes

1

Description

pain score based on visual assessment score (VAS)

Timepoint

before and after injection

Method of measurement

VAS (Visual assessment score) for pain assessment

Secondary outcomes

1

Description

accuracy of injection site

Timepoint

after injection

Method of measurement

fluoroscopic guided imaging as gold standard

Intervention groups

1

Description

Intervention group: at first under guidance of sonography a needle inserted into transforaminal space, then the position of needle checked by fluoroscope. then 1.5 ML of lidocaine 1% and 2ML of triamcinolone 40% injected into space. then the pain score measures with VAS score at 1st, 3rd, 7th dyas and also fist and 3rd months after injection.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital, Babol, Iran

Full name of responsible person

Behnam Baghianimoghadam
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Behnam Baghianimoghadam
Position

Assistant Professor
Latest degree
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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

this study is about a new sonographic guided injection technique and we prefer to save our new innovation until its publication

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

final results could be share

When the data will become available and for how long

immediately after results publication

To whom data/document is available

there is no limit to access

Under which criteria data/document could be used

there is no limit to access

From where data/document is obtainable

please email to: Behnam.baghian@gmail.com

What processes are involved for a request to access data/document

we could respond as soon as receive email

Comments