

# 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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behnam.baghian@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Babol University of Medical Sciences  
**Full name of responsible person**  
Mani Falsafi  
**Street address**  
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drmanifalsafi@gmail.com  
**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**  
Specialist  
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## Person responsible for scientific inquiries

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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**