

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### The Comparison effect of caudal & lumbar Epidural Steroid injections for relief of radicular pain

#### Protocol summary

##### Study aim

The Comparison of caudal & lumbar Epidural Steroid injections for relief of radicular pain

##### Design

A randomized clinical trial with parallel groups. 100 patients have randomly divided into intervention groups A and B with a table of random numbers and Randomizer software

##### Settings and conduct

The population of this study was aged 25-60 years old who referred to Ayatollah Rouhani Hospital in Babol. Patients are randomly divided into two Intervention groups with a table of random numbers by computer Group A. Intervention group1: Bupivacaine 0.5% 3.5 ml, Fentanyl 0.5 ml, Depomedrol 2 ml with normal saline 0.9% , single injection at L5-S1 space in sitting position Intervention group2: Bupivacaine 0.5% 3.5 ml, Fentanyl 0.5 ml, Depomedrol 2 ml with normal saline 0.9%, single injection at sacral hiatus in lateral position

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 25-65 years, Radicular low back pain Exclusion criteria: Bleeding disorders, Anticoagulant therapy, local infections, Septicemia, Hypovolemia, Pregnancy, Ankylosing spondylitis, Low back pain, more than 12 month duration

##### Intervention groups

Intervention group1: Bupivacaine 0.5% 3.5 ml, Fentanyl 0.5 ml, Depomedrol 2 ml with normal saline 0.9% , single injection at L5-S1 space in sitting position Intervention group2: Bupivacaine 0.5% 3.5 ml, Fentanyl 0.5 ml, Depomedrol 2 ml with normal saline 0.9%, single injection at sacral hiatus in lateral position

##### Main outcome variables

intensity of pain

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20141121020020N4**

Registration date: **2019-08-28, 1398/06/06**

Registration timing: **retrospective**

Last update: **2019-08-28, 1398/06/06**

Update count: **0**

#### Registration date

2019-08-28, 1398/06/06

#### Registrant information

##### Name

Shahram Seyfi

##### Name of organization / entity

Babol University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3223 8284

##### Email address

sh.seyfi@mubabol.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2011-04-19, 1390/01/30

#### Expected recruitment end date

2012-04-18, 1391/01/30

#### Actual recruitment start date

2011-04-19, 1390/01/30

#### Actual recruitment end date

2012-04-18, 1391/01/30

#### Trial completion date

2012-04-18, 1391/01/30

#### Scientific title

The Comparison effect of caudal & lumbar Epidural Steroid injections for relief of radicular pain

## Public title

the effect of caudal & lumbar Epidural Steroid injections for control of pain

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age 25-65 years Radicular low back pain

### Exclusion criteria:

Bleeding disorders Anticoagulant therapy local infections Septicemia Hypovolemia Pregnancy Ankylosing spondylitis Low back pain more than 12 month duration

## Age

From **25 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **100**

Actual sample size reached: **100**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not 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 Babol University of Medical Sciences

##### Street address

Daneshgah Square, Ganjafrooz Avenue

##### City

Babol

##### Province

Mazandaran

##### Postal code

47176-41367

#### Approval date

2011-04-19, 1390/01/30

#### Ethics committee reference number

MUBABOL.REC.1390.10

## Health conditions studied

### 1

#### Description of health condition studied

Radiculopathy

#### ICD-10 code

M54.1

#### ICD-10 code description

Neuritis or radiculitis

## Primary outcomes

### 1

#### Description

Intensity of pain

#### Timepoint

30 min, 1 week, and 1 month later

#### Method of measurement

Visual Analog Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Bupivacaine 0.5% 3.5 ml, Fentanyl 0.5 ml, Depomedrol 2 ml with normal saline 0.9%, single injection at L5-S1 space in sitting position

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Bupivacaine 0.5% 3.5 ml, Fentanyl 0.5 ml, Depomedrol 2 ml with normal saline 0.9%, single injection at sacral hiatus in lateral position

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah Rouhani Hospital

##### Full name of responsible person

Shahram Seyfi

##### Street address

Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

##### City

Babol

##### Province

Mazandaran

**Postal code**  
47176-41367  
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+98 11 3223 8301  
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ficu\_ss@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Babol University of Medical Sciences  
**Full name of responsible person**  
Reza ghadimi  
**Street address**  
ice-chancellor Of Research, Daneshgah Square,  
Ganjafrooz Avenue  
**City**  
Babol  
**Province**  
Mazandaran  
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47176-41367  
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+98 11 3219 7667  
**Email**  
rezaghadimi@yahoo.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**  
Shahram Seyfi  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**

Ayatollah Rouhani Hospital, Daneshgah Square,  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Babol University of Medical Sciences  
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Assistant professor  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Babol University of Medical Sciences  
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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**

There is still no plan for its publish.

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available