

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza ghadimi
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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
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Other areas of specialty/work
Anesthesiology
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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

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