Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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%و 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 spondilitis, 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%و 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

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Iran (Islamic Republic of)

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+98 11 3223 8284

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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 spondilitis 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 ofBabol 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%و 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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47176-41367
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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
Street address
ice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue
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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
Specialist
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