Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Cervical Epidural Steroid Injection: Parasagittal approach as an alternative to the midline approach in patients with unilateral cervical radicular pain; a comparative randomized clinical trial

Protocol summary

Study aim

Comparing the efficacy of parasagittal and midline techniques of cervical epidural injection in patients with unilateral cervical radicular pain with regard to alleviation of pain and cervical functional disability.

Design

Single-blind randomized comparative clinical trial with two parallel groups with a total of 26 patients

Settings and conduct

Patients with unilateral cervical radicular pain unresponsive to noninvasive treatments who referred to Akhtar hospital, Imam hossein hospital and Shahid Labbafinejad Clinic, underwent cervical epidural injections either with a parasagittal or midline approach. Both patients and physicians who were in charge of data recording were blind to the groups to which the patients were allocated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age between 18 and 65 years 2. Unilateral cervical radicular pain in an upper extremity 3. Pain duration of at least 3 months 4. Pain unresponsive to conservative treatments such as pharmaceutical treatments and physical therapy for 6 weeks Exclusion criteria: 1. Pregnancy 2. Breast feeding 3. Allergy to a study medication 4. Signs/symptoms of cervical myelopathy 5. Signs/symptoms of progressive unstable nerve damage 6. Cervical spinal stenosis 7. Proven psychiatric disorder 8. Coagulopathy 9. Infection at injection site 10. Uncontrolled medical illness eg, hypertension and diabetes

Intervention groups

Patients who received cervical epidural injections with steroid and local anesthetic through either a parasagittal or midline approach.

Main outcome variables

Pain intensity measurement with Numeric Rating Scale (NRS); Evaluation of neck disability with Neck Disability Index (NDI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180524039816N1**
Registration date: **2018-09-24, 1397/07/02**
Registration timing: **retrospective**

Last update: **2018-09-24, 1397/07/02**
Update count: **0**

Registration date

2018-09-24, 1397/07/02

Registrant information

Name

Kasra Dehghan

Name of organization / entity

Country

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zakerihabib@fums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-17, 1397/02/27

Expected recruitment end date

2018-06-01, 1397/03/11

Actual recruitment start date

2018-05-17, 1397/02/27

Actual recruitment end date

2018-06-01, 1397/03/11

Trial completion date
empty

Scientific title
Cervical Epidural Steroid Injection: Parasagittal approach as an alternative to the midline approach in patients with unilateral cervical radicular pain; a comparative randomized clinical trial

Public title
Comparison of parasagittal and midline interlaminar epidural steroid injections in unilateral cervical radicular pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Unilateral upper extremity radicular pain due to a cervical disc pathology Pain duration of at least 3 months Pain unresponsive to conservative treatment such as medical and physical therapy for 6 weeks Patients' age between 18 and 65 years
Exclusion criteria:
Pregnancy Breast feeding Allergy to one of medications used in the study Signs and symptoms of cervical myelopathy Sings and symptoms indicating a progressive, unstable nerve damage Cervical spinal canal stenosis Proven psychiatric disorder Coagulopathy Infection at the site of injection Presence of an uncontrolled medical problem eg, high blood pressure, diabetes

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **26**
Actual sample size reached: **26**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients received cervical epidural injections either with a parasagittal or a midline approach. Computerized random allocation of patients into one the two groups was done using a random allocation software.

Blinding (investigator's opinion)
Double blinded

Blinding description
Since patients could not see the needle entry point and needle entry points in the two methods used in this study were very close (no more than a few millimeters apart), patients were blind about the group to which they were allocated. Physicians conducting the procedures knew the type of procedure (parasagittal vs midline) they were about to perform on patients and were not blinded to the procedure. Physicians who recorded the pre- and post-intervention data were not aware of the groups to which the patients were allocated.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Akhtar Hospital, Shariati st, Poeroomi, Sharifimanesh st, Azar alley
City
Tehran
Province
Tehran
Postal code
1964714953

Approval date
2018-05-16, 1397/02/26

Ethics committee reference number
IR.SBMU.RETECH.REC.1397.528

Health conditions studied

1

Description of health condition studied
Unilateral cervical radicular pain

ICD-10 code
M50.1

ICD-10 code description
Cervical disc disorder with radiculopathy

Primary outcomes

1

Description
Pain severity measured by NRS (Numeric Rating Scale)

Timepoint
Before and one month after the intervention

Method of measurement
Pain severity according to NRS (Numeric Rating Scale)(Zero to 10; 0 indicating no pain and 10 indicating the worst conceivable pain)

2

Description
Degree of neck disability measured by NDI (Neck

Disability Index)

Timepoint

Before and one month after the intervention

Method of measurement

Degree of neck disability measured with NDI (Neck Disability Index) (expressed as percent)

Secondary outcomes

1

Description

Evaluation of radiocontrast spread pattern in parasagittal and midline cervical epidural injections

Timepoint

At the time of the procedure

Method of measurement

Pattern of radiocontrast spread describe as (1) predominantly midline, (2) predominantly ipsilateral to the painful side, (3) predominantly contralateral to the painful side

Intervention groups

1

Description

Control group: Cervical epidural steroid and local anesthetic injection with the midline approach

Category

Treatment - Other

2

Description

Intervention group: Cervical epidural steroid and local anesthetic injection with the parasagittal approach

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar Hospital

Full name of responsible person

Dr Seyyed Masoud Hashemi

Street address

Shariati st, Poeroomi, Sharifimanesh st, Azar alley

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Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Dr Mehrdad Taheri

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3

Recruitment center

Name of recruitment center

Shahid Labbafinejad Speciality Polyclinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Rezghi

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Kasra Dehghan
Position
In-traning fellow
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Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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