

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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

Iran (Islamic Republic of)

##### Phone

+98 21 2261 2252

##### Email address

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 Signs 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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1964714953

##### **Phone**

+98 21 2261 2252

##### **Email**

dehghan19kasra@gmail.com

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Imam Hossein Hospital

##### **Full name of responsible person**

Dr Mehrdad Taheri

##### **Street address**

Shahid Madani street

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1617763141

##### **Phone**

+98 21 7758 3043

##### **Email**

dehghan19kasra@gmail.com

### 3

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Labbafinejad Speciality Polyclinic

##### **Full name of responsible person**

Dr Peyman Dadkhah

##### **Street address**

Boostan Hashtom, Pasdaran street

##### **City**

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##### **Province**

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##### **Postal code**

1666663111

##### **Phone**

+98 21 2360 2567

##### **Email**

dehghan19kasra@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Dr Afshin Rezghi

##### **Street address**

Shahid Arabi Ave, Daneshjoo Blvd, Velenjak

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1983963113

##### **Phone**

+98 21 2243 9780

##### **Email**

mpajouhesh@sbmu.ac.ir

##### **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-training fellow

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Akhtar Hospital, Shariati st, Poleroomi, Sharifimanesh st, Azar alley

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Dr Kasra Dehghan

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**Email**

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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