

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

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

Tehran

Province

Tehran

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

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2261 2252

Email

dehghan19kasra@gmail.com

Person responsible for scientific 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

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2261 2252

Email

dehghan19kasra@gmail.com

Person responsible for updating data**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

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2261 2252

Email

dehghan19kasra@gmail.com

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