

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation of The Efficacy of Epidural Injection in Patients With Cervical Radiculopathy Based on MRI Imaging

Protocol summary

Study aim

Evaluation of the patients with chronic cervical radiculopathy treated with epidural injection based on MRI and JOACMEQ scoring system

Design

There is a single group in this study. The sample size includes all patients who enter within two months of the start of the project (at least 30patients).

Settings and conduct

Patients failed to respond to maintenance treatment for a month or more are referred to pain ward through a neurosurgeon. Informed written consent is obtained from all patients. Cervical disc classification based on MRI, pain assessment through NRC and VAS, and JOACMEQ rank are evaluated. Then patients undergo epidural injection. One month after the injection, NRC and VAS and the JOACMEQ rating will be reevaluated. The side effects of using epidural steroids will be recorded. The Outcome will be presented after the evaluation of the results.

Participants/Inclusion and exclusion criteria

inclusion criteria: History of unilateral upper extremity radicular pain due to cervical intervertebral disc herniation (confirmed by MRI). Failure to respond to maintenance therapies (such as physical therapy, exercise, and medication) in the past six months. Exclusion Criteria: Coagulation disorder. Sensory and motor disorders in the upper limbs. Needle entry site infection. Degenerative spondylolysis. History of mental illness. History of adverse reactions to steroids or local anesthetics. History of neck surgery. History of drug abuse

Intervention groups

Patients with cervical radiculopathy referred to Imam Hossein Hospital, Tehran within two months of the start of this research who have not been treated with maintenance therapies eg. physical therapy, exercise and medication in the past six months, if desired to be treated with epidural injection and will enter this study

upon their consent. No control group

Main outcome variables

Pain; Quality of life

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20130518013364N10**

Registration date: **2022-04-12, 1401/01/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-12, 1401/01/23**

Update count: **0**

Registration date

2022-04-12, 1401/01/23

Registrant information

Name

Mehrdad Taheri

Name of organization / entity

Shahid Beheshti University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 7756 7840

Email address

m.taheri@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of The Efficacy of Epidural Injection in Patients With Cervical Radiculopathy Based on MRI Imaging

Public title
Evaluation of The Efficacy of Epidural Injection in Patients With Cervical Radiculopathy Based on MRI Imaging

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years History of unilateral upper limb radicular pain due to cervical intervertebral disc herniation confirmed by MRI imaging Failure in responding to maintenance therapies such as physical therapy, exercise, and medication in the past six months
Exclusion criteria:
Coagulation disorder5. 6. 7. 8. History of mental illness9. Patients with a, local anesthetics10. History of neck surgery11. Sensory and motor disorders in the upper limbs Infection at the site of needle entry Degenerative spondylolysis History of adverse reactions to steroids History of adverse reactions to local anesthetics History of neck surgery History of drug abuse

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

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

Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran highway, Shahid Beheshti University Of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1617763141

Approval date

2022-01-30, 1400/11/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.865

Health conditions studied

1

Description of health condition studied

Cervical radiculopathy

ICD-10 code

M50.1

ICD-10 code description

Cervical disc disorder with radiculopathy

Primary outcomes

1

Description

pain

Timepoint

At the beginning of the study ie. before the epidural injection and one month after the epidural injection

Method of measurement

Visual Analogue Scale

2

Description

Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire (JOACMEQ) score

Timepoint

At the beginning of the study ie. before the epidural injection and one month after the epidural injection

Method of measurement

Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire (JOACMEQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In these patients, the combination of 2 cc of Triamcinolone 80 mg and 3 cc of Ropivacaine and 0.2% plus 3 cc of distilled water with a total volume of 7 cc is prescribed via intralaminar injection of cervical epidural. Amp Triamcinolone is made by Elixir Pharmaceutical Company and Amp Ropivacaine is imported by Sina Pishgam Daroo Novin the product of Bioindustria Laboratorio Italiano Medicinali S.p.A

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pain Clinic, Imam Hossein Hospital

Full name of responsible person

Mehrdad Taheri, MD

Street address

Shahid Madani Str

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 0000

Email

m.taheri@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarqi

Street address

Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran highway

City

Tehran

Province

Tehran

Postal code

1985717434

Phone

+98 21 2243 9951

Email

mpd@sbmu.ac.ir

Web page address

<https://research.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

Mehrdad Taheri

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Hossein Hospital, Shahid Madani Street

City

Tehran

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+98 21 7343 0000

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Person responsible for scientific inquiries

Contact

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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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable