

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of changes in electromyography findings before and after treatment in patients with upper extremity radicular pain due to cervical discopathy which has been treated with cervical epidural steroid injection

Protocol summary

Study aim

Evaluation of Electromyographic and clinical findings before and after treatment in patients with radicular upper extremities pain due to cervical discopathy who underwent cervical epidural steroids injections as treatment

Design

The present study is a before and after clinical trial, not blinded, without randomization and phase 2. A total of 40 patients with chronic neck pain will be enrolled.

Settings and conduct

This study will be done in the operating room and clinic. Before and after steroid injection, The clinical characteristics of pain, neuropathic elements and mobility and functional status are evaluated for up to 6 months using different questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with chronic neck pain (more than 3 months), caused by disc herniation or central spinal stenosis, according to the clinical criteria and MRI findings. Exclusion criteria: Age less than 18 years, Prior cervical epidural injections during last year, Prior cervical spinal surgery, All contraindications to steroids or Non-steroidal anti-inflammatory drugs, All contraindications to epidural injections, All red flags for spinal pain (inflammation, malignancy, spinal fracture, myelopathy, cauda equina syndrome), Serious co-morbidities (renal or hepatic failure, severe heart failure, severe respiratory disease, vascular insufficiency), Critical level of spinal stenosis, Ankylosing spondylitis or other rheumatological diseases, Pregnancy and Patient's refusal.

Intervention groups

Interlaminar epidural injection of methylprednisolone 40-80 mg combined with bupivacaine 0.2% at a total volume of 6ml, under fluoroscopic guidance at the C4-C5 or C5-C6 level, via an 18G Tuohy epidural needle.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101113005172N5**

Registration date: **2023-02-14, 1401/11/25**

Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**

Update count: **0**

Registration date

2023-02-14, 1401/11/25

Registrant information

Name

Saman Asadi

Name of organization / entity

Anesthesiology ward of Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1231 8072

Email address

asadisa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-01, 1401/12/10

Expected recruitment end date

2023-09-01, 1402/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of changes in electromyography findings before and after treatment in patients with upper extremity radicular pain due to cervical discopathy which has been treated with cervical epidural steroid injection

Public title

Evaluation of cervical epidural steroid injection in the Improvement of patients with upper extremity radicular pain due to cervical discopathy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with chronic neck pain(more than 3 months), caused by disc herniation or central spinal stenosis, according to the clinical criteria and MRI findings

Exclusion criteria:

All red flags for spinal pain (inflammation, malignancy, spinal fracture, myelopathy, Cauda equina syndrome) Serious coexisting neurological or musculoskeletal disorders Serious comorbidities (renal or hepatic failure, severe heart failure, severe respiratory disease, vascular insufficiency) Rheumatoid arthritis Ankylosing spondylitis or other rheumatological diseases Prior cervical spinal surgery Prior cervical epidural injections during last year All contraindications to epidural injections (Systemic infection or local infection at the site of injection, bleeding diathesis or full anticoagulation, significant allergic reaction/hypersensitivity to contrast, anesthetic, ...) Critical level of spinal stenosis. All contraindications to steroids or Non-steroidal anti-inflammatory drugs Age less than 18 years Pregnancy Patient's refusal

AgeFrom **18 years** old**Gender**

Both

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **40****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 Shiraz Medical School

Street address

3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2022-07-19, 1401/04/28

Ethics committee reference number

IR.SUMS.MED.REC.1401.292

Health conditions studied**1****Description of health condition studied**

Cervical discopathy

ICD-10 code

M50.10

ICD-10 code description

Cervical disc disorder with radiculopathy, unspecified cervical region

Primary outcomes**1****Description**

Pain

Timepoint

10 to 15 days before epidural steroid injection and 1, 3 and 6 months after epidural steroid injection.

Method of measurement

In respect to standardized questionnaire.

2**Description**

electromyogram

Timepoint

10 to 15 days before epidural steroid injection and 1, 3 and 6 months after epidural steroid injection.

Method of measurement

In respect to standardized questionnaire.

Secondary outcomes

empty

Intervention groups

<https://emamreza.sums.ac.ir/>

1

Description

Intervention group: Changes in electromyography findings before and after Interlaminar epidural injection (including: methylprednisolone 40-80 mg combined with bupivacaine 0.2% at a total volume of 6ml, under fluoroscopic guidance at the C4-C5 or C5-C6 level, via an 18G Tuohy epidural needle) will be reviewed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Abu-Ali Sina Hospital

Full name of responsible person

Mahsa Tahvili

Street address

No958, Pasdaran Blvd, Boostan Blvd, Sadra City

City

Shiraz

Province

Fars

Postal code

7199467985

Phone

+98 71 3344 0000

Fax

+98 71 3643 0038

Email

abualisinacharity@gmail.com

Web page address

<http://abualisina.net>

2

Recruitment center

Name of recruitment center

Emam Reza (AS) clinic

Full name of responsible person

Mahsa Tahvili

Street address

Namazee Square, Emam Reza (AS) clinic.

City

Shiraz

Province

Fars

Postal code

7134814734

Phone

+98 71 3212 7000

Fax

+98 71 3647 4673

Email

motahari@sums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Mahtab Memarpour

Street address

7th floor, central building of Shiraz University of Medical Sciences, Vice Chancellor of research, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3235 7282

Fax

+98 71 3212 2430

Email

memarpour@sums.ac.ir

Web page address

<https://rde.sums.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mahsa Tahvili

Position

physician /anesthesiology fellowship

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

tahvili_m@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Saman Asadi

Position

Assistant Professor of Pain Anesthesiology

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

asadisa@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hamide Saeedizade

Position

Research Assistant

Latest degree

Bachelor

Other areas of specialty/work

Medical Informatics

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

0098-36281460

Email

saeedi.hamide@gmail.com

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

It is against our policy

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

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

No - There is not a plan to make this available