Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Age
From **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

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
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No958, Pasdaran Blvd, Boostan Blvd, Sadra City
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2

Recruitment center
Name of recruitment center
Emam Reza (AS) clinic
Full name of responsible person
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Namazee Square, Emam Reza (AS) clinic.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Mahtab Memarpoor
Street address
7th floor, central building of Shiraz University of Medical Sciences, Vice Chancellor of research, Zand street
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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
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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Research Assisstant

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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