

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

evaluation of the efficacy of hyaluronidase and steroid epidural injection compared with hypertonic saline and steroid epidural injection in the treatment of lumbosacral spinal stenosis

Protocol summary

Study aim

Determination of the efficacy of hyaluronidase and steroid epidural injection compared with hypertonic saline and steroid epidural injection

Design

In this research , 30 eligible patients will be divided randomly into two groups. First group will receive saline 5% 15cc, methylprednisolone 80 mg, and marcaine 4cc while the second group will receive hyaluronidase 1500 IU , methylprednisolone 80 mg, and marcaine 4cc.the injection will be done under fluoroscopic guide and after contrast media injection to confirm the best site for injection . appropriate life style and low back exercise will be educated to both groups. Both groups will complete VAS , oswestry disability index and quebec back pain disability scale questionnaires before the procedure and 2, 4 and 8 weeks after procedure. The data will be statistically analyzed by a person who will be blinded to the treatment to compare these 2 methods in pain reduction and improving patient's function.

Settings and conduct

Chamran hospital, Shiraz, Fars , Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.Patients with lumbosacral spinal stenosis who have pain and other clinical symptoms didn't respond to conservative management ; Age between 45 - 75 years old ; Complete and sign constant form Exclusion criteria: Simultaneous radiculopathy ; Diabetes mellitus ; Rheumatologic disease such as collagen vascular disease , SLE , gout ; Simultaneous neuropathy ; Brucella infection ; BMI> 42 ; Knee arthroplasty in affected side ; Coagulopathy ; Allergy to medication ; Hepatic , renal or cardiac failure ; Cancer ; Pregnancy ; Inability to complete questionnaire and poor cooperation ; patients who are under anticoagulant therapy

Intervention groups

Epidural injection under fluoroscopic guide , First intervention group will receive saline 5% 15cc, methylprednisolone 80 mg, and marcaine 4cc while the second group will receive hyaluronidase 1500 IU , methylprednisolone 80 mg, and marcaine 4cc.the injection will be done under fluoroscopic guide and after contrast media injection to confirm the best site for injection . appropriate life style and low back exercise will be educated to both groups.

Main outcome variables

Pain reduction ; Functional improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171106037267N2**

Registration date: **2018-02-10, 1396/11/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-10, 1396/11/21**

Update count: **0**

Registration date

2018-02-10, 1396/11/21

Registrant information

Name

anis ghorbani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 3235 6034

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Recruitment status

Recruitment complete

Funding source
research deputy of shiraz university of medical sciences

Expected recruitment start date
2017-12-22, 1396/10/01

Expected recruitment end date
2018-02-20, 1396/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
evaluation of the efficacy of hyaluronidase and steroid epidural injection compared with hypertonic saline and steroid epidural injection in the treatment of lumbosacral spinal stenosis

Public title
effect of hyalorunidase and steroid epidural injection in lumbar spinal stenosis treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with lumbosacral spinal stenosis who have pain and other clinical symptoms didn't respond to conservative management Age between 45 to 75 y/o Complete and sign constant form Exclusion
Exclusion criteria:
Diabetes mellitus Rheumatologic disease such as collagen vascular disease , SLE , gout Simultaneous radiculopathy Simultaneous neuropathy Brucella infection BMI> 42 Knee arthroplasty in affected side Coaglopathy Inability to complete questionnaire and poor cooperation Allergy to medication Hepatic , renal or cardiac failure Pregnancy Cancer Patients who are receiving Anticoagulant

Age
From **45 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized Block Design with statistical software

Blinding (investigator's opinion)
Double blinded

Blinding description
patients and researcher(who complete the questionnaire) don't know type of injection drug

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
•Ethics committee of Shiraz University of Medical SciencesShiraz University of Medical Sciences
Street address
Central building of Shiraz University of Medical Sciences
City
Shiraz
Province
Fars
Postal code
14336 - 71348
Approval date
2017-11-13, 1396/08/22
Ethics committee reference number
IR.SUMS.MED.REC.1396.102

Health conditions studied

1

Description of health condition studied
Lumbosacral spinal stenosis
ICD-10 code
M48.06
ICD-10 code description
Spinal stenosis, lumbar region

Primary outcomes

1

Description
Patient's pain
Timepoint
Before injection , 2, 4 and 8 weeks after injection
Method of measurement
Visual Analogue Scale , Quebec back pain disability scale and Oswestry disability index questionnaire

2

Description
Functional improvement
Timepoint
Before injection , 2, 4 and 8 weeks after injection
Method of measurement

Quebec back pain disability scale and Oswestry disability index questionnaire

Secondary outcomes

1

Description

Quality of life improvement

Timepoint

Before injection , 2, 4 and 8 weeks after injection

Method of measurement

Quebec back pain disability scale and Oswestry disability index questionnaire

2

Description

Decrease analgesic usage

Timepoint

Before injection , 2, 4 and 8 weeks after injection

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group: will receive hyaluronidase 1500 IU , methylprednisolone 80 mg, and marcaine 4cc.the injection will be done under fluoroscopic guide and after contrast media injection to confirm the best site for injection . appropriate life style and low back exercise will be educated to both groups

Category

Treatment - Drugs

2

Description

Control group: Control group will receive saline 5% 15cc, methylprednisolone 80 mg, and marcaine 4cc .The injection will be done under fluoroscopic guide and after contrast media injection to confirm the best site for injection . appropriate life style and low back exercise will be educated to both groups

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital

Full name of responsible person

Dr Alireza Ashraf

Street address

next to Nyayesh Blvd.Chamran highway

City

Shiraz

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Postal code

7134814336

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An_ghorbani@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Alireza Ashraf

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Central building of Shiraz University of Medical Sciences , Imam Hossein Square , Zand Blvd.,

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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

Dr Alireza Ashraf

Position

Professor of Shiraz University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Shiraz University of Medical Sciences

Full name of responsible person

Dr Alireza Ashraf

Position

Professor of Shiraz University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr Alireza Ashraf

Position

Profesor of Shiraz University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Web page address**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