Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Ḍetermination 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 hyalorunidase 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 constent 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 ; Coaglopathy ; 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 hyalorunidase 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)

Phone

+98 71 3235 6034

Email address

an_ghorbani@sums.ac.ir

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 constent 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
Befor 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 hyalorunidase 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
Province
Fars
Postal code
7134814336
Phone
+98 71 3231 9040
Email
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
Street address
Central building of Shiraz University of Medical Sciences , Imam Hossein Square , Zand Blvd.,
City
Shiraz
Province
Fars
Postal code
14336 - 71348
Phone
+98 71 3232 9040
Email
an_ghorbani@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
Dr Alireza Ashraf
Position
Professor of Shiraz University of Medical Sciences
Latest degree
Specialist

Other areas of specialty/work
Physical Medicine
Street address
Central building of Shiraz University of Medical Sciences , Imam Hossein Square , Zand Blvd.,
City
Shiraz
Province
Fars
Postal code
14336 - 71348
Phone
+98 71 3231 9040
Fax
Email
an_ghorbani@sums.ac.ir
Web page address

Person responsible for scientific 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
Street address
Central building of Shiraz University of Medical Sciences., Imam Hossein Square , Zand Blvd.,
City
Shiraz
Province
Fars
Postal code
14336 - 71348
Phone
+98 71 3231 9040
Fax
Email
an_ghorbani@sums.ac.ir
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
Street address
Central building of Shiraz University of Medical Sciences., Imam Hossein Square , Zand Blvd.,
City
Shiraz
Province
Fars
Postal code
14336 71348
Phone
+98 71 3231 9040
Fax
Email
an_ghorbani@sums.ac.ir
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