

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

A comparison between effectiveness of gluteal trigger injection with epidural steroid injection in lumbosacral canal stenosis patients

Protocol summary

Study aim

A comparison between effectiveness of gluteal trigger points injection with epidural steroid injection in lumbosacral canal stenosis patients

Design

the research is a randomize double blind clinical trial

Settings and conduct

The patients who had lumbosacral canal stenosis were selected from Emam Reza clinic and Rajaee hospital, then patients were divided into two groups and after obtaining written consent the study was begun. In the control group, steroid was injected into epidural, and in the intervention group, steroid was injected in the gluteal trigger points. Then its effects on reducing patients' pain and improving function were measured.

Participants/Inclusion and exclusion criteria

Exclusion criteria: Infection involving lumbar spinal (brucella), Diabetes mellitus, Rheumatological disorder (lupus, gout), BMI more than 42, Pregnancy, Malignancy, Liver disease, History of allergies, Malnutrition, Peripheral neuropathy, Bleeding disorder, Galactosemia, Radiculopathy. Inclusion criteria: Age: 40-75 years old, Being diagnosis with lumbar canal stenosis according to MRI or EDX, Complaining low back pain, pseudoclaudication, paresthesia that no responded to conservative treatment, Sex: male or female

Intervention groups

Group 1: received an injection of steroid into gluteal trigger points. Group 2: received steroid epidural injection under fluoroscopic guide.

Main outcome variables

pain, activity of daily living

General information

Reason for update

1-Date transfer: Due to the delay in the acceptance and approval process and we expected a shorter time, we

started the sick time earlier. 2. Being blind on both sides due to a typographical error

Acronym

IRCT registration information

IRCT registration number: **IRCT20190802044411N1**

Registration date: **2020-11-26, 1399/09/06**

Registration timing: **prospective**

Last update: **2021-05-20, 1400/02/30**

Update count: **1**

Registration date

2020-11-26, 1399/09/06

Registrant information

Name

Sana Khoshnazar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3875 2488

Email address

khoshnazar31@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2022-03-10, 1400/12/19

Actual recruitment start date

2020-11-27, 1399/09/07

Actual recruitment end date

2021-03-18, 1399/12/28

Trial completion date

2021-05-14, 1400/02/24

Scientific title

A comparison between effectiveness of gluteal trigger

injection with epidural steroid injection in lumbosacral canal stenosis patients

Public title

Gluteal trigger point injection in lumbosacral canal stenosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age : 40 to 75 years old Being diagnosis with lumbar canal stenosis according to mri or edx Complaining low back pain , psudoclaudication , parestesia that no responded to conservative treatment Gender: male or female

Exclusion criteria:

Infection involving lumbar spinal (brucella) Diabetes mellitus Rhumatological disorder(lupuse, gout) BMI more than 42 Pregnancy Malignancy Liver disease sensitivity reaction to test drug Malnutrition Peripheral neuropathy Bleeding disorder Galactosemia Radiculopathy

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Complete randomized block design with random allocation software was used for randomization and the list of patients was prepared by a computer with the same block length and the secretary divided the patients based on the list of patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

clinical caregiver: we taught the caregiver how to complete the questionnaire. this person was not aware of the allocation to groups. The outcome assessor who completed the questionnaires was not aware of the group allocation. Data analyzer: Questionnaires were finally given to a person to review the information. This person does not know any of the steps of the work, how groups were classified and the intervention performed.

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 Sciences

Street address

No.6, Baharan Ave , Maali abad Blvd

City

shiraz

Province

Fars

Postal code

7184747811

Approval date

2019-06-22, 1398/04/01

Ethics committee reference number

IR.SUMS.MED.REC.1398.221

Health conditions studied

1

Description of health condition studied

lumbosacral canal stenosis

ICD-10 code

M99.53

ICD-10 code description

Intervertebral disc stenosis of neural canal of lumbar region

Primary outcomes

1

Description

radicular low back pain

Timepoint

two weeks, four weeks, eight weeks

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

function of patient

Timepoint

two weeks, four weeks , eight weeks

Method of measurement

The Quebec Back Pain Disability Scale

Intervention groups

1

Description

Intervention group: The group that received 80 mg Amp

Methylprednisolon and 4 cc Amp Marcaine epidural injection with fluoroscopic guidance and then two weeks , four weeks, eight weeks after first dose injection , VAS, Oswestry, Quebec , RMQ was filled.

Category

Rehabilitation

2

Description

Control group: The group that received injection of 80 mg Methylprednisolon amp and 5 cc of lidocaine amp in gluteal trigger points, then two weeks, four weeks and eight weeks after first dose, VAS, Oswestry, Quebec, RMQ questionnaires were filled.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam reza rehabilitation clinic

Full name of responsible person

Mani Ramzi

Street address

Namazi square

City

Shiraz

Province

Fars

Postal code

714737-71348

Phone

+98 71 3212 7700

Email

motahari@sums.ac.ir

2

Recruitment center

Name of recruitment center

Rajae hospital

Full name of responsible person

Amirreza Mesbahi

Street address

Chamran Blvd

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Postal code

7194815711

Phone

+98 71 3636 4001

Email

Rajaeehospital@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Ghasemi

Street address

Khalili Aveno, front of Maaref school

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7134814336

Phone

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Email

Info@sums.ac.ir

Grant name

Grant code / Reference number

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

No

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

Sana Sadat Khoshnazar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Khoshnazar31@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All available data can be shared after making people unidentifiable

When the data will become available and for how long

start access period one year after publishing the results

To whom data/document is available

everyone can access to this information

Under which criteria data/document could be used

if the information in this study helps to improve the science process

From where data/document is obtainable

khoshnazar31@yahoo.com 00989131434549

What processes are involved for a request to access data/document

after sending the desired message, all authors of the study will be consulted all information will be sent within a maximum of the three weeks if permitted.

Comments