Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of two doses of hyaluronidase in the outcome of epidural steroid injection in patients with failed back surgery syndrome

Protocol summary

Study aim
Determining the effectiveness of epidural injection of two different doses of hyaluronidase in the outcome of patients with back surgery failure syndrome

Design
A clinical trial with a control group, with parallel groups. Two blind strains. Phase 3 was randomized on 40 patients and balanced block was used for randomization.

Settings and conduct
It is an intervention study and a clinical trial type. The sample size is 40 people. Patients with low back pain syndrome in the operating room of Shahid Beheshti Hospital, Qom and after obtaining written consent, are divided into two groups by randomization using block randomization method: The first group includes 20 patients who received caudal and transforaminal epidural injections. hyaluronidase are placed. The second group of 20 patients will undergo caudal epidural and transforaminal hyaluronidase injection.

Participants/Inclusion and exclusion criteria
Entry requirements: age older than18 years old; patients who have not responded satisfactorily to 6 weeks of medical treatment despite the annoying pain NRS>=5. Non-entry conditions: prohibition of withdrawal of hyaluronidase due to allergy; nerve damage and vascular collagen diseases; bleeding disorders and anticoagulant use.

Intervention groups
The control group, after obtaining consent, qualified people, in the form of random sampling, under aseptic conditions, epidural caudal and transforaminal hyaluronidase 1500 IU (HYL) and triamcinolone 80 mg. The intervention group, after obtaining consent, qualified people, in the form of random sampling, under aseptic conditions, epidural caudal and transforaminal injection of hyaluronidase 3000 IU (HYL) and triamcinolone 80 mg.

Main outcome variables
Pain level; disability level

General information

Reason for update

Acronym
FBSS

IRCT registration information
IRCT registration number: **IRCT20240827062876N1**
Registration date: **2024-09-05, 1403/06/15**
Registration timing: **prospective**

Last update: **2024-09-05, 1403/06/15**
Update count: **0**

Registration date
2024-09-05, 1403/06/15

Registrant information

Name
mahsa mehrabi

Name of organization / entity

Country
Iran (Islamic Republic of)

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bem_beg88@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-20, 1403/08/30

Expected recruitment end date
2025-05-21, 1404/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of two doses of hyaluronidase in the outcome of epidural steroid injection in patients with failed back surgery syndrome

Public title
Epidural injection of hyaluronidase in failed back surgery syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Candidate patients to remove adhesions with medication Age older than 18 years History of epidural steroid injection in the last six months Patients who have not responded satisfactorily to 6 weeks of medical treatment despite the annoying pain NRS>=5 The presence of evidence of pressure on the lumbar spinal cord in MRI

Exclusion criteria:
Hyaluronidase contraindications Symptoms of cauda equina, spinal canal stenosis requiring surgery, psychosomatic disease suffering from diabetes; Suffering from rheumatic diseases and vascular collagen and gout and lupus Having nerve damage and neuropathies Suffering from bleeding diseases Inability to communicate History of allergies and allergic reactions to the drugs used History of significant liver, kidney and cardio-pulmonary disorders Pregnancy Suffering from cancers

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be assigned to intervention and control groups using block randomized method. The link "https://www.sealedenvelope.com/simple-randomiser/v1/lists" will be used for block randomization. For this purpose, the target number of samples (40 samples), number of groups (two groups A and B) and number of blocks (4) will be entered and the system will provide the researcher with a list of 4 blocks. Based on the output list, it will be determined in which group the patients who enter the study should be placed in order. Items A represent the intervention group and items B represent the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Based on the block randomization method, patients will be divided into two control and intervention groups of 20 people. In a group of anesthesiologists who will not know the type of research, patients will be given epidural injections under one of two doses of the drug based on the sealed envelope in which the drug dose is specified. The principal investigator will not know which patient is receiving which block. The patient and the person filling the questionnaire do not know the type of block.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Qom University of Medical Sciences

Street address
No. 83, Shahid Lotfi Niaser Ave, Safashehr Blvd

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Province
Ghoum

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3719964797

Approval date
2024-01-15, 1402/10/25

Ethics committee reference number
IR.MUQ.REC.1402.223

Health conditions studied

1

Description of health condition studied
Failed back surgery syndrome

ICD-10 code
M96.1

ICD-10 code description
Postlaminectomy syndrome, not elsewhere classified

Primary outcomes

1

Description
Pain Level

Timepoint
Two weeks, one month, three months and six months after treatment

Method of measurement
Numeric Rating Scale (NRS) (0 None; 1-3 Mild; 4-7 Moderate; 8-10 Severe)

2

Description
Disability Level
Timepoint
Two weeks, one month, three months and six months after treatment
Method of measurement
Oswestry Low Back Disability Questionnaire that disability is measured with 10 items. Each item is scored from 5-0, which indicates a higher score for the disability.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: after obtaining consent, qualified people, in the form of random sampling, under aseptic conditions, epidural caudal and transforaminal injection of hyaluronidase 3000 IU (HYL) and triamcinolone 80 mg.
Category
Treatment - Drugs

2

Description
Control group: after obtaining consent, qualified people, in the form of random sampling, under aseptic conditions, epidural caudal and transforaminal hyaluronidase 1500 IU (HYL) and triamcinolone 80 mg.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital
Full name of responsible person
mahsa mehrabi
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Sponsors / Funding sources

1

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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
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
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Position
Associate Professor
Latest degree
Subspecialist
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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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable