Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of hyaluronidase Vs. hypertonic saline 5% effects in Percutaneous Caudal Epidural Adhesiolysis With the Racz Technique for patients with Failed Back Surgery Syndrome

Protocol summary

Study aim
Comparison of hyaluronidase Vs. hypertonic saline 5% effects in Percutaneous Caudal Epidural Adhesiolysis With the Racz Technique for patients with Failed Back Surgery Syndrome

Design
Clinical trial with intervention and control groups, 60 patients sample size, Trial phase 2-3

Settings and conduct
Tertiary regional and teaching hospital. Participants including major eligibility criteria, among the patients who were candidates for epidural injection with the Racz Technique referred to the Akhtar Hospital in 2019, 60 were selected by Sequential method, and accidentally divided into two groups of control and intervention according to the random numbers table.

Participants/Inclusion and exclusion criteria
Inclusion criteria : Age 18 and above ; Epidural Adhesion Detection Based on Clinical and MRI Findings ; History of chronic low back pain after surgery for more than six months . Exclusion criteria: Facet joint arthritis ; Lumbar disc degenerative

Intervention groups
Intervention group: Injection of bupivacaine 0.25% (8 ml), triamcinolone 40 mg (1 ml), normal saline 0.9% (2 ml), hyaluronidase 1500 IU via Racz catheter Control group: Injection of bupivacaine 0.25% (8 ml), triamcinolone 40 mg (1 ml), normal saline 0.9% (2 ml), hypertonic saline 5% via Racz catheter

Main outcome variables
Pain Level; disability.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131124015515N7**
Registration date: **2019-07-28, 1398/05/06**
Registration timing: **prospective**

Last update: **2019-07-28, 1398/05/06**
Update count: **0**

Registration date
2019-07-28, 1398/05/06

Registrant information

Name
Masoud Hashemi

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 2261 2252

Email address
dr.hashemi@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-31, 1398/05/09

Expected recruitment end date
2020-02-18, 1398/11/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of hyaluronidase Vs. hypertonic saline 5% effects in Percutaneous Caudal Epidural Adhesiolysis

With the Racz Technique for patients with Failed Back Surgery Syndrome

Public title
Comparison of the Effect of Hyaluronidase and Hypertonic Saline 5% on Removal lumbar spinal space adhesion

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 and above Epidural Adhesion Detection Based on Clinical and MRI Findings History of spinal surgery History of chronic low back pain after surgery for more than six months Radicular or axial back pain Herniated disk Patients with satisfaction to participate in the study

Exclusion criteria:
Facet joint arthritis History of epidural injection or other invasive treatments in the last six months Severe central lumbar canal stenosis Stenosis caused by scoliosis Lumbar disc degenerative Sacroiliac joint disease Severe cardiopulmonary disease, uncontrolled diabetes, obesity History of misuse of any type of narcotic, opioid and alcohol Pregnancy, breastfeeding Psychiatric problems and patient's lack of cooperation, speech problems Surgical indication Topical skin infections in the area of the surgery Coagulation disorder Contraindication for Epidural Lumbar Injection Patients dissatisfied with participation in the study

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization based on random numbers table, in this method, we set a set of numbers without a specific pattern and order, and completely randomly in the table, we will read the table numbers from the direction above. For the intervention group, we consider the even numbers and the control group for the odd numbers. Then put on one of the numbers and move upwards, register the number and assign one to an intervention or control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participant and clinical outcomes evaluator are not aware of the code assigned to each of the groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Tabnak St.,Tehran, Tehran, Iran, Islamic Republic Of

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2019-05-04, 1398/02/14

Ethics committee reference number
IR.SBMU.REC.1398.008

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
Before treatment, one, three and six months after treatment

Method of measurement
visual analog scale (VAS) (0 None; 1-3 Mild; 4-7 Moderate; 8-10 Severe)

2

Description
Disability Level

Timepoint
Before treatment, one, three 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 placing the Racz catheter under fluorescope and determining the location of the lesion, 10-20 ml of saline solution with 1500 IU of hyaluronidase, 0.25% of bupivacaine and triamcinolone 40 mg are introduced into the epidural space of the caudal through the Racz catheter.
Category
Treatment - Drugs

2

Description
Control group: After placing the Racz catheter under fluorescope and determining the location of the lesion, 10-20 ml of hypertonic saline 5%, 0.25% of bupivacaine and triamcinolone 40 mg are introduced into the epidural space of the caudal through the Racz catheter.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhtar Hospital
Full name of responsible person
Masoud Hashemi MD
Street address
Pain Clinic, Akhtar Hospital, Sharifi Manesh st.
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Tehran
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1964714953
Phone
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Email
dr.hashemi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi MD.
Street address
Shahid Arabi st., Yaman St., Shahid Chamran Expressway
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zarghi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Masoud Hashemi MD.
Position
Associate Professor
Latest degree
Subspecialist
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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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
The whole data can be shared after unidentifiable people.
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Only available to scholars working in academic and academic institutions
Under which criteria data/document could be used
Employed in research centers
From where data/document is obtainable
Person responsible for scientific inquiries
What processes are involved for a request to access data/document
Send email to person responsible for scientific inquiries
Comments