Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of caudal volume injecton on optic nerve sheath diameter in pateints with failed back surgery syndrome

Protocol summary

Study aim
Effect of caudal injection on the diameter of the optic nerve sheath in patients with failed back surgery syndrome

Design
A clinical trial study on 46 patients without a control group, not randomized from July9,2024 to January9, 2024

Settings and conduct
In the pain department of Imam Hossain Hospital of Shahid Behshti University of Medical Sciences ,after obtaining written consent and absence of exclusion criteria, age, sex, body mass index ,systolic, diastolic and mean arterial blood pressure and heart rate, as well as optic nerve sheath diameter are measured with a linear ultrasound probe before caudal injection in the supine position and are recorded.Then, for all patients with failed lumbar surgery syndrome, 30 ml containing 1500 units of hyaluronidase and normal saline in a volume of 10 ml, 40 mg of methylprednisolone and %0.2 ropivacaine to a volume of 10 ml and after 20 minutes, 10 ml of 5% sodium chloride is injected in prone position in the caudal epidural space using a 22-gauge spinal cutting needle and ultrasound guidance.Then, in supine position immediately and in 10, 20 and 40 minutes after the caudal injection,above parameters are measured .

Participants/Inclusion and exclusion criteria
Inclusion criteria:Patients between the ages of 18 and 60 to treatment of failed back surgery syndrome with using caudal injection .Exclusion criteria: coagulation disorders, infection in the sacrum ,systemic infection

Intervention groups
Patients aged 18 to 60 to the treatment of failed back surgery syndrome with using caudal epidural injection

Main outcome variables
Change in intracranial pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240609062049N1**
Registration date: **2024-09-28, 1403/07/07**
Registration timing: **registered_while_recruiting**

Last update: **2024-09-28, 1403/07/07**
Update count: **0**

Registration date
2024-09-28, 1403/07/07

Registrant information

Name
Sayed mohammad reza Razavizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5533 9217

Email address
mr_razavi48@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-05, 1403/04/15

Expected recruitment end date
2025-01-04, 1403/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of caudal volume injecton on optic nerve sheath diameter in pateints with failed back surgery syndrome

Public title
Effect of caudal volume injection on optic nerve sheath diameter

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 18 to 60 years Suffering from failed back surgery syndrome Candidate for epidural adhesion removal by caudal epidural injection

Exclusion criteria:
coagulation disorders occupational brain lesions Increased intracranial pressure infection of sacrum area systemic infections optic nerve diseases cauda equina syndrome cerbrovascular diseases uncontrolled arterial hypertension ischemic heart disease and or cardiac arrythmias

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Shahid madani street - Emam hossain hospital

City
Tehran

Province
Tehran

Postal code
6314116177

Approval date
2024-06-02, 1403/03/13

Ethics committee reference number
IR.SBMU.RETECH.REC.1403.077

Health conditions studied

1

Description of health condition studied
Optic nerve sheath diameter

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Optic nerve sheath diameter

Timepoint
Before intervention, immediately,10,20,40 minutes after intervention

Method of measurement
ultrasonography

2

Description
optic nerve sheath diameter

Timepoint
pervious , ultimate , 10 ,20 and 40 minutes after caudal iniection

Method of measurement
ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 30 ml of solution containing 1500 units of hyaluronidase made by WOCKHARDT.UK in a volume of 10 ml within 2 minutes, 10 ml of rovacaine 0.2% made by Varian pharmed along with 40 mg of methylprednisolone made by Iranhormone pharmaceutical co. within 2 minutes and then From 20 minutes, 10 ml of 5% sodium chloride manufactured by SAMEN Pharmaceutical Co. It is injected once in 2 minutes in the caudal epidural space.Send feedback

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam hosain hospital

Full name of responsible person
Sayed mohammad reza razavizadeh

Street address
Shahi madani street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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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
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
Sayed mohammad reza razavizadeh

Position
Associate professor

Latest degree
Specialist

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)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Because the data is specific to this study and cannot be given to other researchers from an ethical point of view.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available