Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Safety and feasibility of selective dorsal rhizotomy in patients with spinal cord injury-induced spasticity

Protocol summary

Study aim

The present study aims to assess the safety and feasibility of selective dorsal rhizotomy in patients with spinal cord injury-induced spasticity.

Design

This study is a single arm, nonblinded, nonrandomized, phase 1 clinical trial on 15 patients to assess the safety and feasibility of study intervention.

Settings and conduct

A total of 15 patients will undergo selective dorsal rhizotomy in the present single-arm clinical trial. Since the aim of this study is to assess the safety and feasibility of the intervention, randomization and blinding will not be performed. Patients will be evaluated regarding the study outcomes at baseline, 1-week, 3-, and 6-month postoperatively.

Participants/Inclusion and exclusion criteria

Patients with cervical or thoracolumbar complete spinal cord injury (SCI)-induced intractable spasticity refractory to treatment for at least six months, modified Ashworth scale of at least three, and spasm frequency score of at least two will be included. Patients who have spasticity with etiologies other than SCI, concurrent traumatic brain injury, or a history of prior therapy with intrathecal baclofen will be exculded.

Intervention groups

A total of 15 patients with complete spinal cord injury-induced spasticity, will undergo selective dorsal rhizotomy. The procedure includes laminectomy or laminoplasty followed by partial division of dorsal nerve roots using intraoperative neurophysiologic monitoring.

Main outcome variables

The primary outcome measure of the study was the safety profile of the study intervention. Secondary outcome measures included modified Ashworth scale, spasm frequency scale, spinal cord injury spasticity evaluation tool, visual analog scale for spasticity, spinal cord independence measure, and Short Form 36 Health Survey Questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200502047277N7**
Registration date: **2022-04-04, 1401/01/15**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-04, 1401/01/15**
Update count: **0**

Registration date

2022-04-04, 1401/01/15

Registrant information

Name

saeed oraee yazdani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-28, 1401/01/08

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and feasibility of selective dorsal rhizotomy in patients with spinal cord injury-induced spasticity

Public title
Selective dorsal rhizotomy in spinal cord injury-induced spasticity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Modified Ashworth scale (MAS) of at least 3 and spasm frequency score (SFS) of at least 2 Patients with intractable spasticity after at least 6 months therapy with oral antispasmodic agents Candidates for intrathecal baclofen infusion who could not receive this therapy Age greater than 18 years Complete spinal cord injury or American Spinal Injury Association impairment scale (AIS) grade A Written informed consent obtained from the patient
Exclusion criteria:
Any brain lesion in areas involved in coordination or posture, such as basal ganglia or cerebellum based on MR imaging Any form of movement disorders, such as dyskinesia, dystonia, or ataxia Concurrent traumatic brain injury Genetic etiology for spasticity, such as hereditary spastic paraplegia Any evidence of a progressive neurological disorder Treatment with oral antispasmodic agents for less than six months Prior therapy with intrathecal baclofen pump Pregnancy or lactation Participation in another study during the present study period
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Not randomized
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 Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences ,Shahid Arabi St., Yemen St., Shahid Chamran Highway, Tehran
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Province
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1985717443
Approval date
2020-05-16, 1399/02/27
Ethics committee reference number
IR.SBMU.RETECH.REC.1399.580

Health conditions studied

1

Description of health condition studied
Injury of nerves and spinal cord at neck level
ICD-10 code
S14
ICD-10 code description
Injury of nerves and spinal cord at neck level

2

Description of health condition studied
Unspecified injury of thoracic spinal cord
ICD-10 code
S24.10
ICD-10 code description
Unspecified injury of thoracic spinal cord

Primary outcomes

1

Description
Safety profile of the study intervention
Timepoint
Baseline, 1-week, 3- and 6-month postoperatively
Method of measurement
Monitoring and evaluating the patients regarding the adverse events

Secondary outcomes

1

Description
Modified Ashworth scale (MAS)
Timepoint
Baseline, 1-week, 3- and 6-month postoperatively
Method of measurement
Physical examination and using the 6-point scale

2

Description
Spasm frequency scale (SFS)
Timepoint
Baseline, 1-week, 3- and 6-month postoperatively
Method of measurement
A self-report 5-point measure

3

Description
Spinal cord injury spasticity evaluation tool (SCI-SET)
Timepoint
Baseline and 6-month postoperatively
Method of measurement
Self-report questionnaire including 35 items

4

Description
Visual analog scale (VAS) for spasticity
Timepoint
Baseline, 1-week, 3- and 6-month postoperatively
Method of measurement
100 mm visual analog scale

5

Description
Spinal cord independence measure (SCIM)
Timepoint
Baseline and 6-month postoperatively
Method of measurement
Scoring using the measure based on clinical observation

6

Description
Short Form 36 Health Survey Questionnaire (SF-36)
Timepoint
Baseline and 6-month postoperatively
Method of measurement
Short Form 36 Health Survey Questionnaire (SF-36)

Intervention groups

1

Description
Intervention group: All patients in this study will undergo selective dorsal rhizotomy (SDR). The procedure includes partial section and division of dorsal nerve roots selected using intraoperative neurophysiologic monitoring. L1 to S1 nerve roots will be divided into rootlets of equal size. After that, electrical stimulation will be applied using intraoperative neurophysiologic monitoring and rootlets with greatest reflex responses will be cut.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
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Shohadaye Tajrish Hospital
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Sponsors / Funding sources

1

Sponsor
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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
Roozbeh Tavanaei

Position
Research associate

Latest degree
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Other areas of specialty/work
Neurosurgery

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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
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