

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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 excluded.

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

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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 City Tehran Province Tehran Postal code 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

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Saeed Oraee Yazdani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Afshin Zarghi

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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

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

Medical doctor

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