

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

Country

Iran (Islamic Republic of)

Phone

+98 21 25719

Email address

saeed_o_yazdani@sbmu.ac.ir

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

Street address

Shohadaye Tajrish hospital, Tajrish Square.

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

Saeed_o_yazdani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Building Number.2, Shahid Beheshti University of Medical Sciences, Arabi Avenue, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2243 9770

Email

Intl_office@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

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

Street address
Functional Neurosurgery Research Center (FNRC),
SBMU Shohada-E-Tajrish Educational Hospital, Tajrish
Sq., Tehran, Iran
City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2270 1022

Email

rtavanaei@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saeed Oraee Yazdani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Shohadaye Tajrish Hospital, Tajrish Ave.

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Roozbeh

Position

Research associate

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address
Functional Neurosurgery Research Center (FNRC),
SBMU Shohada-E-Tajrish Educational Hospital, Tajrish
Sq., Tehran, Iran
City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2270 1022

Email

rtavanaei@sbmu.ac.ir

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