

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparisons of the effects of Baclofen, Transcutaneous Electrical Nerve Stimulation and sustain stretch for the treatment of spasticity in the traumatic spinal cord injury

Protocol summary

Study aim

1. To compare the effect of baclofen, TENS & sustain stretch for spasticity management in spinal cord injury.
2. To determine the Range of Motion of ankle joint

Design

Randomized Clinical Trail

Settings and conduct

Paraplegic Centre Peshawar. single blinded

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Spasticity (Grade ≥ 1 and ≤ 4 as per MAS) 2. Have sustained a traumatic spinal cord injury a Minimum of 3 months before consent. 3. Age = 20 - 45 years Exclusion criteria: 1. Have chronic systemic diseases and have any other serious co-morbidity, e.g. hepatitis C, infections and Deep vein thrombosis etc. 2. Have extensive fixed contractures in the lower limbs 3. Have any contraindications to Baclofen, TENS and sustain stretch such as experience clinically significant orthostatic Hypo-tension in response to electrical stimulation or allergies or Have a history of bone fracture or family history of fragility fractures

Intervention groups

1. Group (I) (oral anti-spasticity drug treatment group): 2. Group (II) (TENS treatment group): 3. Group (III) (Sustain stretch treatment group):

Main outcome variables

Spasticity

General information

Reason for update

Acronym

Spasticity Management in Spinal Cord Injury (SMSCI)

IRCT registration information

IRCT registration number: **IRCT20210615051585N1**

Registration date: **2021-07-01, 1400/04/10**

Registration timing: **retrospective**

Last update: **2021-07-01, 1400/04/10**

Update count: **0**

Registration date

2021-07-01, 1400/04/10

Registrant information

Name

Saima Gul

Name of organization / entity

Shifa Tameer - e - Millat University

Country

Pakistan

Phone

+92 51 8441751

Email address

saimagul.ahs@stmu.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-12, 1399/12/22

Expected recruitment end date

2021-06-15, 1400/03/25

Actual recruitment start date

2021-03-12, 1399/12/22

Actual recruitment end date

2021-06-09, 1400/03/19

Trial completion date

2021-06-09, 1400/03/19

Scientific title

Comparisons of the effects of Baclofen, Transcutaneous Electrical Nerve Stimulation and sustain stretch for the treatment of spasticity in the traumatic spinal cord injury

Public title

Comparisons of the effects of Baclofen, Transcutaneous Electrical Nerve Stimulation and sustain stretch for the

treatment of spasticity in the traumatic spinal cord injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Spasticity (Grade ≥ 1 and ≤ 4 as per MAS) 2. Have sustained a traumatic spinal cord injury a Minimum of 3 months before consent 3. Age = 20 - 45 years

Exclusion criteria:

1. Have chronic systemic diseases and have any other serious co-morbidity, e.g. hepatitis C, infections and Deep vein thrombosis etc. 2. Have extensive fixed contractures in the lower limb 3. Have any contraindications to Baclofen, TENS and sustain stretch such as experience clinically significant orthostatic Hypotension in response to electrical stimulation or allergies or Have a history of bone fracture or family history of fragility fractures

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **127**

Actual sample size reached: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment for treatment

Blinding (investigator's opinion)

Single blinded

Blinding description

Only the researcher doing the study knows which treatment or intervention the participant is receiving. It makes results less likely to be biased.

Placebo

Not used

Assignment

Other

Other design features

N/A

Secondary Ids

1

Registry name

N/A

Secondary trial Id

N/A

Registration date

2021-06-09, 1400/03/19

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board and Ethics Committee (IRB and EC) Shifa International Hospital and Shifa

Street address

Department of Rehabilitation Sciences, Dar ul Shifa Campus, Shifa Tameer e Millat University

City

Islamabad

Postal code

25000

Approval date

2021-05-18, 1400/02/28

Ethics committee reference number

IRB#082-21

Health conditions studied

1

Description of health condition studied

Traumatic Spinal Cord Injury

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Spasticity

Timepoint

baseline, 1st week, 2nd week, 3rd week & 4th week after intervention

Method of measurement

Modified Ashworth Scale

Secondary outcomes

1

Description

To determine the Range of Motion (ROM) of ankle joint

Timepoint

4th week

Method of measurement

secondary outcome will be measured through Goniometer

Intervention groups

1

Description

Intervention group: Baclofen

Category

Treatment - Drugs

2

Description

Intervention group: Transcutaneous Electrical Nerve Stimulation (TENS)

Category

Treatment - Devices

3

Description

Intervention group: Sustain Stretch

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Paraplegic Centre Peshawar

Full name of responsible person

Dr. Bazmeer Afridi

Street address

Sector P 1, Street 10, Phase 4 Hayatabad, Peshawar
Khyber Pakhtunkhwa, Pakistan

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Peshawar

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Email

bazmeer.afridi786@gmail.com

Web page address

<https://paraplegiccenter.org/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shifa Tameer e Millat University

Full name of responsible person

Dr. Saima Gul

Street address

Department of Rehabilitation Sciences, Dar ul Shifa
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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

Shifa Tameer e Millat University

Proportion provided by this source

100

Public or private sector

Private

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

Shifa Tameer e Millat University

Full name of responsible person

Dr. Saima Gul

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

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Person responsible for scientific inquiries

Contact

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Shifa Tameer e Millat University

Full name of responsible person

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person
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Latest degree
Ph.D.
Other areas of specialty/work
Rehabilitation Management
Street address
Department of Rehabilitation Sciences, Dar ul Shifa
Campus, Shifa Tameer e Millat University
City

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

Due to Ethical Considerations

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