

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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  $\geq 1$  and  $\leq 4$  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  $\geq 1$  and  $\leq 4$  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

#### City

Peshawar

#### Postal code

25000

#### Phone

+92 91 9217901

#### Fax

+92 91 9217901

#### 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  
Campus, Shifa Tameer e Millat University

#### City

Islamabad

#### Postal code

44000

#### Phone

+92 51 8441751

#### Email

saimaa.gul@gmail.com

#### 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

#### Street address

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## Person responsible for scientific inquiries

### Contact

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#### Latest degree

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Rehabilitation Management

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## Person responsible for updating data

### 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  
**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