Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Paraplagic 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 Hypo-tension 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 traetment

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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Phone
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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
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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
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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