

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of Transcutaneous electrical nerve stimulation at two frequencies on Urinary Incontinence in post stroke patients; A Randomized controlled trial

#### Protocol summary

##### Study aim

In order to investigate the effect of different frequencies of TENS in urinary incontinence the current study was planned as no such study was done in not only Pakistan but Asia. The study will investigate the effect of TENS at two frequencies among patients post-stroke urinary symptoms.

##### Design

Randomised, superiority, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site

##### Settings and conduct

Rehman Medical Institute, Peshawar

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Patients of age <60 years 2. Patients of both genders Exclusion Criteria: 1. Patients with urinary retention, 2. Patients with a history of UI for various reasons (Parkinson's disease, spinal cord disease, dementia, urinary tract tumours, urolithiasis, unhealed urinary tract infections, or a history of urinary tract surgery),

##### Intervention groups

Experimental Group (Group A): The patients in group 1 will receive therapy with TENS for 30 mins once daily for 4 weeks in the hospital (as inpatients or outpatients). The TENS currents will be biphasic square waves with pulse durations of 150  $\mu$ secs and pulse frequencies of 75 Hz. Control Group (Group B): The patients in group 2 will receive therapy with TENS for 30 mins once daily for 4 weeks in the hospital (as inpatients or outpatients). The TENS currents will be biphasic square waves with pulse durations of 150  $\mu$ secs and pulse frequencies of 20 Hz.

##### Main outcome variables

Tools to be used are Overactive Bladder Symptom Score (OABSS)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221112056475N1**

Registration date: **2022-11-15, 1401/08/24**

Registration timing: **prospective**

Last update: **2022-11-15, 1401/08/24**

Update count: **0**

##### Registration date

2022-11-15, 1401/08/24

##### Registrant information

##### Name

Sarmad Saeed Khattak

##### Name of organization / entity

Rehman Medical Institute, Peshawar

##### Country

Pakistan

##### Phone

+92 91 5838666

##### Email address

sarmad.saeed@rmi.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-23, 1401/09/02

##### Expected recruitment end date

2023-02-23, 1401/12/04

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Effects of Transcutaneous electrical nerve stimulation at two frequencies on Urinary Incontinence in post stroke patients; A Randomized controlled trial

### Public title

Effects of Transcutaneous electrical nerve stimulation at two frequencies on Urinary Incontinence in post stroke patients; A Randomized controlled trial

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients with UI after stroke Patients who were stable, cooperative, and could effectively communicate (to participate in therapy Patients who could complete the survey on urination both before and after treatment

#### Exclusion criteria:

Patients with urinary retention Patients with a history of UI for various reasons (Parkinson's disease, spinal cord disease, dementia, urinary tract tumours, urolithiasis, unhealed urinary tract infections, or a history of urinary tract surgery) Patients who needed significant fluid infusions or drugs that affected urination Patients with concurrent serious organic diseases Patients with severe cognitive functioning disorders (Mini-Mental State Examination10 score <22 points)

### Age

To 60 years old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Outcome assessor

### Sample size

Target sample size: 98

### Randomization (investigator's opinion)

Randomized

### Randomization description

Following the selection of patients and the assessment of baseline similarities, the included participants will be randomly assigned to the control and experimental groups using the sealed envelopes method.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Due to the nature of the study, blinding the researcher/therapist and subjects will not be feasible. However, the assessor, who will compare pre and post scores will be blinded.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Advance Studies & Research Board (AS&RB)

##### Street address

F1 Phase-6 Rd, Phase 5 Hayatabad, Peshawar, Khyber Pakhtunkhwa 25100

##### City

Peshawar

##### Postal code

25100

#### Approval date

2022-11-13, 1401/08/22

#### Ethics committee reference number

KMU/IPMR/MSPT/007

## Health conditions studied

### 1

#### Description of health condition studied

Urinary Incontinence

#### ICD-10 code

N39.4

#### ICD-10 code description

Other specified urinary incontinence

## Primary outcomes

### 1

#### Description

Overactive Bladder Symptom Score (OABSS)

#### Timepoint

Pre intervention and after 4 weeks of intervention

#### Method of measurement

Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The patients in group 1 will receive therapy with TENS (model EN-Stim 4; ENRAF-NONIUS Company Ltd, Rotterdam, the Netherlands) for 30 mins once daily for 4 weeks in the hospital (as inpatients or outpatients). The TENS device will use a four-channel stimulator with fully independent channels and four sets of moist pads for rubber electrodes (6 × 8 cm). This process will make it possible to treat major muscle

groups simultaneously or to perform bilateral treatments simultaneously. The TENS currents will be biphasic square waves with pulse durations of 150 µsecs and pulse frequencies of 75 Hz.

### Category

Treatment - Devices

## 2

### Description

Control group: The patients in group 2 will receive therapy with TENS (model EN-Stim 4; ENRAF-NONIUS Company Ltd, Rotterdam, the Netherlands) for 30 mins once daily for 4 weeks in the hospital (as inpatients or outpatients). The TENS device will use a four-channel stimulator with fully independent channels and four sets of moist pads for rubber electrodes (6 × 8 cm). This process will make it possible to treat major muscle groups simultaneously or to perform bilateral treatments simultaneously. The TENS currents will be biphasic square waves with pulse durations of 150 µsecs and pulse frequencies of 20 Hz.

### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rehman Medical Institute, Peshawar

##### Full name of responsible person

Zohaib Ali

##### Street address

5-B/2 Shaukat Khanum Rd, Phase 5 Hayatabad, Peshawar, Khyber Pakhtunkhwa 25000

##### City

Peshawar

##### Postal code

25000

##### Phone

+92 91 5838666

##### Email

zohaibali23204@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Khyber Medical University, Peshawar

##### Full name of responsible person

Hazrat Bilal Malakandi

##### Street address

F1 Phase-6 Rd, Phase 5 Hayatabad, Peshawar, Khyber Pakhtunkhwa 25100

##### City

Peshawar

##### Postal code

25100

##### Phone

+92 91 9217703

##### Email

bilal\_kmu02@yahoo.com

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Khyber Medical University, Peshawar

##### 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

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Khyber Medical University, Peshawar

##### Full name of responsible person

Mujeeb Ur Rahman

##### Position

Assistant Professor

##### Latest degree

Master

##### Other areas of specialty/work

Physiotherapy

##### Street address

F1 Phase-6 Rd, Phase 5 Hayatabad, Peshawar, Khyber Pakhtunkhwa 25100

##### City

Peshawar

##### Province

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##### Email

mujeeb.rahman@kmu.edu.pk

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Rehman Medical Institute, Peshawar

##### Full name of responsible person

Sarmad Saeed Khattak

##### Position

Consultant physiotherapist

##### Latest degree

Master

**Other areas of specialty/work**

Physiotherapy

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Peshawar, Khyber Pakhtunkhwa 25000

**City**

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**Person responsible for updating data****Contact****Name of organization / entity**

Khyber Medical University, Peshawar

**Full name of responsible person**

Zohaib Ali

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

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**City**

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**Postal code**

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+92 91 9217703

**Email**

zohaibali23204@gmail.com

**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**

To keep data confidential and not available for copying

**Study Protocol**

No - There is not 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**

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