Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 investigates 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 µsecs 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 µsecs 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

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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 envelops 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

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+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

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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

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

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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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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
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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
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