

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Electrical Stimulation in addition to motor Re-learning Programme on Spasticity and Upper limb Function in Stroke Patients

#### Protocol summary

##### Study aim

The aim of the study is to find the compare the effects of electrical stimulation with and without motor re-learning programme on spasticity and upper limb function in stroke patients

##### Design

Two arm parallel group randomized trial , single blind , of 62 stroke patients

##### Settings and conduct

Sir Ganga Ram Hospital

##### Participants/Inclusion and exclusion criteria

Inclusion criteria was as follows: • Aged between 25-65 years • Both Male and females • Stroke Onset  $\geq 3$  months • Ischemia Stroke • Patients with limb spasticity equal to 2 or less than 2 on modified Ashworth scale • Patients with English reading and writing skills Exclusion Criteria: • Patients with visual and auditory defects • Patients with severe shoulder or wrist pain • Patients with upper limb fractures/dislocations • Contraindication to Electrical stimulation such as skin allergy

##### Intervention groups

Both groups will receive electrical stimulation for 15 minutes with hot pack and the Stretching of muscles will be performed at the end. The sessions will be last 60 minutes five days a week for an 8-week period. Electrical stimulation will be used to stimulate flexion and extension of wrist and elbow. In Group A participants will receive electrical stimulation with motor relearning programme which consist of 4 steps as Step 1: Analysis of Task Step 2: Practice of missing component Step 3: Practice of Task Step 4: Transference of training In Group B Electrical stimulation without motor re-learning programme will be given. This protocol will be as including different exercises like Wrist flexion and extension, Finger flexion and extension, Forearm supination and pronation, tapping table top with all fingers, Opening of all fingers and Counting with fingers. These exercises which can be performed for 5-10 repetitions depending on patient's capacity.

#### Main outcome variables

Spasticity Upper limb function neurological function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240914063038N1**

Registration date: **2024-09-26, 1403/07/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-09-26, 1403/07/05**

Update count: **0**

##### Registration date

2024-09-26, 1403/07/05

##### Registrant information

##### Name

Nimra Zulfaqar

##### Name of organization / entity

University of Lahore

##### Country

Pakistan

##### Phone

+92 324 4569208

##### Email address

nimrazulfaqar1122@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-03-07, 1402/12/17

##### Expected recruitment end date

2024-10-10, 1403/07/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Electrical Stimulation in addition to motor Re-learning Programme on Spasticity and Upper limb Function in Stroke Patients

**Public title**  
Electrical Stimulation in addition to motor Re-learning Programme on Spasticity and Upper limb Function in Stroke Patients

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Aged between 25-65 years Both Male and females Stroke Onset ≥3 months Ischemia Stroke Patients with limb spasticity equal to 2 or less than 2 on modified Ashworth scale Patients with English reading and writing skills  
**Exclusion criteria:**  
Patients with visual and auditory defects Patients with severe shoulder or wrist pain Patients with upper limb fractures/dislocations Contraindication to Electrical stimulation such as skin allergy

**Age**  
From **25 years** old to **65 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  

- Outcome assessor

**Sample size**  
Target sample size: **62**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Simple randomization will be used by one of the research team members who will be blinded to study and will not be involved in patient recruitment. Participants will be randomly allocated into two groups through lottery method

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
This study is a single blinded study in which outcome assessor will be unaware of the treatment group

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of University of Lahore

##### Street address

University of Lahore Teaching Hospital Lahore ,  
Punjab , Pakistan

##### City

Lahore

##### Postal code

55150

#### Approval date

2024-02-15, 1402/11/26

#### Ethics committee reference number

REC-UOL-672-03-2024

## Health conditions studied

### 1

#### Description of health condition studied

Stroke is a neurological disorder characterized by blockage of blood vessels. Clots form in the brain and interrupt blood flow, clogging arteries and causing blood vessels to break, leading to bleeding. Rupture of the arteries leading to the brain during stroke results in the sudden death of brain cells owing to a lack of oxygen.

#### ICD-10 code

I63.30

#### ICD-10 code description

Cerebral infarction due to thrombosis of unspecified cerebral artery

## Primary outcomes

### 1

#### Description

The Modified Ashworth Scale is a clinical assessment tool used to measure the spasticity of muscles in individuals with neurological conditions, such as cerebral palsy, stroke, multiple sclerosis, or spinal cord injuries.

#### Timepoint

8th weeks

#### Method of measurement

The Modified Ashworth Scale typically uses a 6-point grading system to assess muscle tone. The scale ranges from 0 to 4 with an additional grade of 1+. Where 0 means normal and 4 severe spasticity

### 2

#### Description

The Motor evaluation scale for upper extremity in stroke (MESUPES) measures quality of movement performance of the hemiparetic arm and hand in stroke patients. MESUPES is comprised of 17 items in two subscales: MESUPES-Arm function: 8 items with 6 response categories (0-5) and other one is MESUPES-Hand

function: 9 items with 3 response categories (0-2).

#### **Timepoint**

8th weeks

#### **Method of measurement**

The maximum achievable score is 58 (MESUPES-Arm maximum score is 40; MESUPES-Hand maximum score is 18). The patient is awarded one score for each task, and the highest score is retained. A score of 0 is awarded when the patient demonstrated inadequate tone, abnormal muscle contractions, synergic (flexor/extensor) or mass movement patterns.

## **Secondary outcomes**

### **1**

#### **Description**

The National Institutes of Health Stroke Scale (NIHSS) is a widely used clinical tool for assessing the severity of stroke-related neurological deficits. It was developed by the National Institute of Neurological Disorders and Stroke (NINDS) and is utilized to evaluate the status of patients who have experienced a stroke or other cerebrovascular events.

#### **Timepoint**

8th weeks

#### **Method of measurement**

The NIHSS consists of a series of 11 neurological examination items, and each item assesses specific functions related to different areas of the brain. Each item is scored on a scale from 0 to 3 or 0 to 4, depending on the specific item. A higher score indicates a more severe neurological deficit. The scores from each item are then added together to give a total NIHSS score, which can range from 0 (no stroke-related deficits) to 42 (maximum severity). (Zöllner et al., 2020)

## **Intervention groups**

### **1**

#### **Description**

Intervention Group : Group A will be received electrical stimulation for 15 minutes with hot pack and the stretching of muscles will be performed at the end. The sessions will be last 60 minutes five days a week for an 8-week period. The parameter of the stimulation (Comfystim®) will be included a frequency of 35HZ, Synced option of EMS, pulse width of 250µ, Asymmetrical biphasic waveform, duty cycle of 5 secs on and 5secs off, and the amplitude was adjusted to the maximal tolerance of patient .To stimulate wrist flexion, active electrode was placed over the flexor carpi radialis and the indifferent electrode over the flexor carpi ulnaris. To stimulate Elbow flexion, active electrode over the biceps and the indifferent electrode over the brachialis. To stimulate wrist and finger extension the active electrode will be positioned over extensor digitorum communis (EDC) and the indifferent electrode over extensor pollicis longus (EPL) and abductor pollicis longus (AbPL). To stimulate extension of the arm, active electrode will be placed over the anterior deltoid and the

indifferent electrode over the triceps. The participants randomly will be allocated in Group A received the Motor Re-learning Programme with electrical stimulation. Motor re-learning programme which included different types of task specific exercises (3 reps & 10 times) will be performed. This motor re-learning programme includes following steps as treatment plans : Step 1: Analysis of Task Step 2: Practice of missing component Step 3: Practice of Task Step 4: Transference of training

#### **Category**

Other

### **2**

#### **Description**

Intervention group B: In Group B Electrical stimulation without motor re-learning programme will be given for 60 mins on the upper limb for five days per week for a period of 8th weeks. First 15 minutes' hot pack with electrical stimulation will be applied. The stimulation parameters and electrode placements will be the same as those previously mentioned. And upper limb Stretches of long finger flexors, Wrist flexors, Thumb adductors, Forearm pronators, Adductors and Internal rotators of GH joint were performed. Home Based Programme: This protocol will be including different exercises like Wrist flexion and extension, Finger flexion and extension, Forearm supination and pronation, tapping table top with all fingers, Opening of all fingers and Counting with fingers

#### **Category**

Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Sir Ganga Ram Hospital

##### **Full name of responsible person**

Momna Asghar

##### **Street address**

Mozang Rd, Block B Jinnah Town, Lahore, Punjab 54000

##### **City**

Lahore

##### **Postal code**

55150

##### **Phone**

+92 304 7487995

##### **Email**

momnaasghar@uipt.uol.edu.pk

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

University of Lahore

##### **Full name of responsible person**

Nimra Zulfaqar

**Street address**

University of Lahore Teaching Hospital Lahore ,  
Punjab , Pakistan

**City**

Lahore

**Postal code**

55150

**Phone**

+92 324 4569208

**Email**

nimrazulfaqar4569@gmail.com

**Web page address**

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

None

**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**

University of Lahore

**Full name of responsible person**

Nimra Zulfaqar

**Position**

Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

University of Lahore Teaching Hospital Lahore ,  
Punjab , Pakistan

**City**

Lahore

**Province**

Punjab

**Postal code**

55150

**Phone**

+92 324 4569208

**Email**

nimrazulfqar4569@gmail.com

**Person responsible for scientific**

**inquiries**

**Contact**

**Name of organization / entity**

University of Lahore

**Full name of responsible person**

Nimra Zulfaqar

**Position**

Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

University of Lahore Teaching Hospital Lahore ,  
Punjab , Pakistan

**City**

Lahore

**Province**

Punjab

**Postal code**

55150

**Phone**

+92 324 4569208

**Email**

nimrazulfqar4569@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

University of Lahore

**Full name of responsible person**

Nimra Zulfaqar

**Position**

Punjab

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

University of Lahore Teaching Hospital Lahore ,  
Punjab , Pakistan

**City**

Lahore

**Province**

Punjab

**Postal code**

55150

**Phone**

+92 324 4569208

**Email**

nimrazulfqar4569@gmail.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Demographic data and data related to final outcome will be shared by maintaining the confidentiality

**When the data will become available and for how****long**

Data will be available after the publication after the publication of findings till six months

**To whom data/document is available**

Nimra Zulfaqar

**Under which criteria data/document could be used**

For research purpose

**From where data/document is obtainable**

To the corresponding author of the study, Nimra Zulfaqar and can contact on +92324569208  
nimrazulfqar4569@gmail.com

**What processes are involved for a request to access data/document**

Open access and there is the traditional public data release where anyone can get access to the data

**Comments**