Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 ≥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
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University of Lahore
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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 csale 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 radials 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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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 confidentially

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 correspomding author of the stuyd , Nimra Zulfaqar and can contact on +92324569208 nimrazulfqar4569@gmail.com

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

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

Comments