

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Effects of neuromuscular electrical stimulation on motor function of hand in hemiplegic ischemic chronic stroke patients: A randomized controlled trial

Protocol summary

Study aim

The aim of the study is to find out The effectiveness of neuromuscular electrical stimulation on motor function of hand in hemiplegic ischemic chronic stroke patients. The effectiveness of neuromuscular electrical stimulation on strength of hand in hemiplegic ischemic chronic stroke patients.

Design

Randomized, parallel group with single blinded study. Sealed envelopes were used.

Settings and conduct

the trial is conducted in Sheikh Zayed hospital, RYK. Single blinded study design is used in which all the participants are kept blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hemiplegic patients having single episode of ischemic chronic stroke diagnosed by the neurologist. Male and female patients between 40 to 60 years of age.39 Duration of stroke, more than 6 months with spastic paralysis. Exclusion criteria: Participants with unstable condition i.e., recurrent stroke. Implanted electrical devices(pacemaker, defibrillator etc).

Intervention groups

control group will receive routine physical therapy. Experimental group will receive neuromuscular electrical stimulation in addition to routine physical therapy.

Main outcome variables

there are 2 main outcome variables 1.Fugl meyer motor assessment scale 2.Hand held dynamometer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210702051758N1**
Registration date: **2021-08-21, 1400/05/30**

Registration timing: **retrospective**

Last update: **2021-08-21, 1400/05/30**

Update count: **0**

Registration date

2021-08-21, 1400/05/30

Registrant information

Name

anam raza

Name of organization / entity

University of Lahore, Pakistan

Country

Pakistan

Phone

+92 68 5873794

Email address

anamraza2august@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-01, 1399/04/11

Expected recruitment end date

2021-06-30, 1400/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of neuromuscular electrical stimulation on motor function of hand in hemiplegic ischemic chronic stroke patients: A randomized controlled trial

Public title

Effects of neuromuscular electrical stimulation on motor function of hand in hemiplegic ischemic chronic stroke patients: A randomized controlled trial

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

1.Hemiplegic patients having single episode of ischemic chronic stroke diagnosed by the neurologist. Male and female patients between 40 to 60 years of age. Duration of stroke, more than 6 months with spastic paralysis. Participants with no prior physical therapy session for the issue under study. .Participants should be able to understand and follow simple verbal instructions (Mini-Mental Status Examination [MMSE]≥24).

Exclusion criteria:

1.Participants with unstable condition I.e, recurrent stroke. History of congenital deformities and comorbidities. Presence of contractures in the limb under study. Implanted electrical devices(pacemaker, defibrillator etc). Participant of another research trial.

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done using simple random sampling technique. Individual sampling was done with sealed envelopes as tools for randomization. Random sequence was built by chit pull method. Allocation concealment was done.

Blinding (investigator's opinion)

Single blinded

Blinding description

This is a single blinded study. In this study only the participants are kept unaware of the group in which they will be placed.

Placebo

Not used

Assignment

Parallel

Other design features

Randomization of the sample with single blinded study and allocation by sealed envelopes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Lahore

Street address

1-km Defence road, Lahore

City

Lahore

Postal code

54000

Approval date

2021-02-25, 1399/12/07

Ethics committee reference number

IRB-UOL-FAHS/824/2021

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

I63.9

ICD-10 code description

Cerebral infarction, unspecified

Primary outcomes

1

Description

Fugal meyer motor assessment scale

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

functional tasks will be performed

2

Description

Hand held dynamometer

Timepoint

before the intervention and 4 weeks after intervention

Method of measurement

Hand held dynamometer

Secondary outcomes

empty

Intervention groups

1

Description

Control group: the control group will receive routine physical therapy for half hour a day,5 days a week, for 4 weeks. Activities of daily living will be performed to enhance motor function.

Category

Rehabilitation

2

Description

Intervention group: intervention group will receive neuromuscular electrical stimulation in addition to routine physical therapy for half hour. A total of 1 hour therapy session will be given daily, 5 days a week for 4 weeks. A NMES device will be used with a pair of surface electrodes. Indifferent electrode will be secured on the upper arm of the patient while active electrode will be placed on dorsum and volar aspect of hand for 15 minutes each. the frequency of stimulation will be set on 30 Hz. After stimulation, the group will receive routine therapy for another 30 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheikh Zayed hospital, Rahim Yar Khan

Full name of responsible person

Fozia Nawaz

Street address

Hospital road, Rahim Yar Khan

City

Rahim Yar Khan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Lahore

Full name of responsible person

Asad Gillani

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+92 924 2111856

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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

University of Lahore

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

Faiza Shareef

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

Contact

Name of organization / entity
university of Lahore
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Position
student
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available