Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Electrical Muscle Stimulation versus Resisted Exercises in upper limbs muscle Strength and bulk development in paraplegic patients

Protocol summary

Study aim
To determine the effectiveness of resisted exercises and electrical muscle stimulation in upper limbs muscle strength and bulk development in paraplegic patients.

Design
The study was conducted on a total sample of 52 participants divided into two groups; the control and the experimental. Randomized, superiority, parallel-group trial with blinded outcome assessment. Randomization was centralized and computerized with concealed randomization sequence carried out at an external site

Settings and conduct
Paraplegic Center Peshawar

Participants/Inclusion and exclusion criteria
Inclusion criteria: If participants have a sustained spinal cord injury for four weeks and their primary rehabilitation is completed. Aged between 18-30 years Being able to give consent. labeled by their physician as fit and can undertake exercise training program Ischemic stroke of MCA subjects suffering from stroke for at least 6 months. Exclusion criteria: If patients will have Brachial plexus, peripheral nerve injury or current surgery of upper limb since last 2 months. According to the National Pressure Ulcer Advisory Panel classification have stage 3 or 4 sacral ulcer. Have any bone disorder e.g. such as Paget's disease, senile osteoporosis etc. Have a long-term history of fracture in the upper limb.

Intervention groups
Group 1: This group was provided with electrical muscle stimulation intervention. Participants undergone the overall treatment session for two months (8 weeks) and 3 days per week.The total electrical stimulation time was 10 minutes for each Muscle. Group 2: This group were underwent resisted exercises for 8 weeks. During each training session 3 sets were performed. Every training session were started and ended at heart rate of 100 beats per minutes whereas stretching time of 5 minutes.

Main outcome variables
muscle strength and muscle bulk

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220524054977N2**
Registration date: **2022-09-13, 1401/06/22**
Registration timing: **retrospective**

Last update: **2022-09-13, 1401/06/22**
Update count: **0**

Registration date
2022-09-13, 1401/06/22

Registrant information

Name
Wagma Wajid

Name of organization / entity
Rehman Medical Institute, Peshawar

Country
Pakistan

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+92 91 5822632

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wagma.wajid@rmi.edu.pk

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-03, 1400/10/13

Expected recruitment end date
2022-06-04, 1401/03/14

Actual recruitment start date
2022-01-07, 1400/10/17

Actual recruitment end date
2022-06-08, 1401/03/18
Trial completion date
2022-06-11, 1401/03/21

Scientific title
Effectiveness of Electrical Muscle Stimulation versus Resisted Exercises in upper limbs muscle Strength and bulk development in paraplegic patients

Public title
Effectiveness of Electrical Muscle Stimulation versus Resisted Exercises in upper limbs muscle Strength and bulk development in paraplegic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
If participants have a sustained spinal cord injury from four weeks and their primary rehabilitation is completed Age including 18-30 years Participants that are able to give consent Participants that are labeled by their physician as fit and can undertake exercise training program Ischemic stroke of MCA subjects suffering from stroke for at least 6 months
Exclusion criteria:
If the patient will have Brachial plexus, peripheral nerve injury or current surgery of upper limb since last 2 months According to the National Pressure Ulcer Advisory Panel classification. Have stage 3 or 4 sacral ulcer Have any bone disorder e.g. such as Paget's disease, senile osteoporosis etc Have a long-term history of fractures in the upper limb. Have a family history of weakened fractures Suffering from chronic systemic diseases, e.g. hepatitis C or HIV-AIDS Have fixed contractures in the upper extremity Have already pain in upper limb due to any other cause rather than SCI Are likely to experience autonomic hyperreflexia Could suffer from orthostatic hypotension as a result of electrical muscle stimulation Have any other serious medical conditions like malignancies, psychiatric problems
Age
From **18 years** old to **30 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **52**
Actual sample size reached: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
After patients are selected and baseline similarities are assessed, they will be randomly allocated to the control group and experimental group using the sealed envolpe method
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the study, it will not be feasible to blind the researcher/therapist and subjects. However, the assessor, who will assess 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
Institutional Review Board (IRB) of Shifa Tameer-e-Millat University
Street address
Shifa International Hospitals Ltd، Gate No. 1، 4 Pitras Bukhari Rd, H 8/4 H-8, Islamabad, Islamabad Capital Territory
City
Islamabad
Postal code
44000
Approval date
2022-01-02, 1400/10/12
Ethics committee reference number
IRB#276-21

Health conditions studied

1

Description of health condition studied
Paraplagia
ICD-10 code
G82.2
ICD-10 code description
Paraplegia

Primary outcomes

1

Description
Muscle Strength
Timepoint
Before intervention, as baseline, and after 8 weeks of intervention
Method of measurement
3.3.1 MMT (manual muscle testing) or Oxford Scale

2

Description

Muscle size

Timepoint

Baseline and after 8 weeks of intervention

Method of measurement

Measuring Tape

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group was provided with electrical muscle stimulation intervention. Participants undergone the overall treatment session for two months (8 weeks) and 3 days per week. The targeted muscles for electrical stimulation were bicep brachi and triceps brachi. The parameters were as follows, frequency 45 Hertz, Biphasic Symmetrical Square wave with10 second on and 20 second off time. Ramp up time was 3 second, while ramp down timeWas 3 seconds. We used Comfy Stim EV-806 for muscle stimulation. Synchronous Stimulation was applied. The total electrical stimulation time was 10 minutes for each Muscle. The intensity at which tetanic contraction was elicited was used. Two of the EMS electrodes pad was placed on belly and insertion of Bicep muscles and then on Triceps muscles respectively.

Category

Rehabilitation

2

Description

Control group: This group were underwent resisted exercises for 8 weeks. The maximum strength of participants was assessed by one repetition maximum before and after the training session. Two exercises were included: Seated chest press involving pectoralis major and pectoralis minor, triceps brachii and deltoid muscles and Seated arm pull involving latissimus dorsi, trapezius, teres major and minor, rhomboids, deltoids, biceps brachii and brachialis, triceps brachii, pectoralis major and minor, and serratus anterior muscles. During each training session 3 sets were performed. The intensity of these sets was 80% of one repetition maximum. In first and second set, 8 repetitions were performed of two included exercises. In next third set patient will perform repetitions up to muscle fatigue level. If patient were able to perform 12 or more repetitions while performing third set, then work load were increased 5-10% for next treatment session. Two minutes' rest was given after each set performed and 5-minute rest in between both exercises. The concentric and eccentric phases of resistance will last for 3 second each. Every training session were started and ended at heart rate of 100 beats per minutes whereas stretching time of 5 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Paraplagic Center Peshawar

Full name of responsible person

Syed Muhammad Ilyas

Street address

Phase 4, Sector P 1، Street 10, Phase 4 Hayatabad, Peshawar, Khyber Pakhtunkhwa

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Peshawar

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Web page address

https://paraplegiccenter.org/about-us/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shifa Tameer-e-millat university

Full name of responsible person

Syed Ali Hussain

Street address

Shifa International Hospitals Ltd، Gate No. 1، 4 Pitras Bukhari Rd, H 8/4 H-8, Islamabad, Islamabad Capital Territory

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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

Shifa Tameer-e-millat university

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
shifa tameer-e-millat university

Full name of responsible person
Syed Ali Hussain

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Person responsible for scientific inquiries

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Person responsible for updating data

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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 the privacy of the participants

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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable