

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Conjunct effect of supported standing and functional electrical stimulation on strength and functional mobility in acute stroke:A randomized clinical trial

#### Protocol summary

##### Study aim

To determine the conjunct effects of supported standing and functional electrical stimulation on strength and functional mobility in acute stroke.

##### Design

Randomized clinical trial.

##### Settings and conduct

Data was collected from Dr. Ajaz Ali Physical Therapy clinic, and Wahid trust hospital in Gujrat, Punjab Pakistan

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria 1. Patients 30-65 years of age. 2. Adults with acute stroke. 3. Adults with ischemic stroke. 4. Patients able to react on verbal command. 5. Medically stable patient. 6. Patient was able to walk before stroke. Exclusion Criteria Patients were excluded if they have; 1. Unstable cerebral perfusion. 2. Uncontrolled diabetes mellitus, hypertension and associated cardiac problems. 3. Associated problems in the limb e.g., deep vein thrombosis. 4. Any orthopedic condition e.g., arthritis and fractures. 5. If the physiological variables (blood pressure, oxygen, heart rate, temperature) go beyond set safety limits and patients with severe fatigue.

##### Intervention groups

Group A: Receiving both Functional electrical stimulation and weight bearing along with conventional therapy.  
Group B: Receiving early weight bearing along with conventional therapy

##### Main outcome variables

Strength Functional Mobility

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190828044636N1**

Registration date: **2021-01-31, 1399/11/12**

Registration timing: **retrospective**

Last update: **2021-01-31, 1399/11/12**

Update count: **0**

##### Registration date

2021-01-31, 1399/11/12

##### Registrant information

###### Name

Sadia Iftikhar

###### Name of organization / entity

Riphah International University

###### Country

Pakistan

###### Phone

+92 53 3515229

###### Email address

drsipt@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-10, 1396/12/19

##### Expected recruitment end date

2018-09-15, 1397/06/24

##### Actual recruitment start date

2018-03-10, 1396/12/19

##### Actual recruitment end date

2018-09-25, 1397/07/03

##### Trial completion date

2018-12-10, 1397/09/19

##### Scientific title

Conjunct effect of supported standing and functional electrical stimulation on strength and functional mobility in acute stroke:A randomized clinical trial

##### Public title

Effects of Supported Standing and Functional Electrical Stimulation in acute stroke

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients 30-65 years of age. Adults with acute stroke. Adults with ischemic stroke. Patients able to react on verbal command. Medically stable patient. Patient was able to walk before stroke.

### Exclusion criteria:

Unstable cerebral perfusion. Uncontrolled diabetes mellitus, hypertension and associated cardiac problems. Associated problems in the limb e.g., deep vein thrombosis Any orthopedic condition e.g., arthritis and fractures. If the physiological variables (blood pressure, oxygen, heart rate, temperature) go beyond set safety limits and patients with severe fatigue

## Age

From **30 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **58**

Actual sample size reached: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

simple random sampling technique was used .Computer generated randomization technique using the online sequence number generator for random allocation of patients in two groups has been used to collect the data.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Institutional review board of Riphah International University Lahore campus

##### Street address

28-M,Quaid-e-Azam, Industrial Estate, Kot Lakhpat, Lahore

##### City

Lahore

## Postal code

54000

## Approval date

2018-03-10, 1396/12/19

## Ethics committee reference number

Ref.NO.RCRS-RE-MS-NMPT/spring2018/002

## Health conditions studied

### 1

#### Description of health condition studied

stroke

#### ICD-10 code

I63

#### ICD-10 code description

Cerebral infarction

## Primary outcomes

### 1

#### Description

Strength

#### Timepoint

Baseline(before intervention) , After 6 weeks of intervention

#### Method of measurement

Manual muscle testing,The River Mead Mobility Index

## Secondary outcomes

### 1

#### Description

Balance and Functional mobility

#### Timepoint

Baseline(before intervention), After six weeks of intervention

#### Method of measurement

Berge Balance Scale

## Intervention groups

### 1

#### Description

Intervention group:Group A: Participants were treated with conventional therapy (positioning, ROM exercises, bed mobility exercises) along with FES(Functional Electrical Stimulation) and supported standing by using tilt table initially later on standing frames and walkers for 30 minutes once a day and five times a week for six weeks.Stimulation was applied by two channel comfy stimulators (model no EV-806).stimulations was applied by surface electrodes. Electrodes were applied at the points Gluteus Maximus,QuadricepsFemoris, Tibialis Anterior for 10 minutes each. Stimulation was applied at pulse rate of 40 Hz and pulse width of 180  $\mu$ s. Group B: received conventional therapy (positioning, ROM exercises, and bed mobility exercises) along with

supported standing by using tilt table initially later on standing frames and walkers for 30 minutes once a day and five times a week. Both groups received treatment for six weeks.

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Wahid Trust hospital

**Full name of responsible person**

Dr. Abdul Sattar

**Street address**

Wahid Trust Hospital G.T road Gujrat

**City**

Gujrat

**Postal code**

50700

**Phone**

+92 53 3726115

**Email**

drasattar1996@gmail.com

### 2

#### Recruitment center

**Name of recruitment center**

Dr. Ajaz Ali physiotherapy services

**Full name of responsible person**

Dr.Ajaz Ali

**Street address**

Illahi Plaza,opposite Gujrat Gymkhana, Bhimber Road ,gujrat

**City**

Gujrat

**Postal code**

50700

**Phone**

+92 53 3515229

**Email**

ejazalisheikh@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Self

**Full name of responsible person**

Sadia Iftikhar

**Street address**

Dr. ejaz ali physiotherapy services,illahi plaza bhimbhar road gujrat

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**Postal code**

50700

**Phone**

+92 53 3515229

**Fax****Email**

drsipt@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**

self

**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**

Persons

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Riphah International University lahore campus

**Full name of responsible person**

Sadia Iftikhar

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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House no A-3, Muhallah Noor Pur Sharqi, Gujrat

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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Riphah International University Lahore campus  
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50700

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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

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

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

data collected from the primary outcomes only

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

starting 6 months after publications. when it will be published

### To whom data/document is available

people working in academic and clinical practice

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

for clinical trial data can be shared

### From where data/document is obtainable

through email

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

when any one want to review it and request through email then data will be provided

### Comments