

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of Quadriceps muscle activation with Neuromuscular Electrical Stimulation in patients with Congestive heart failure

#### Protocol summary

##### Study aim

The objective of this study will be to evaluate the effects of quadriceps muscle activation with neuromuscular electrical stimulation in patients with congestive heart failure.

##### Design

Two parallel groups, double-blinded, Randomized Controlled Trial with pre and post-assessment. Sample size will be 54.

##### Settings and conduct

The data will be collected from Gulab Devi Hospital, Lahore.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: • 45-60 years of age • Congestive Heart Failure patients • Forced expiratory volume in 1 second (FEV1) less than 50% predicted • Incapacitating breathlessness (Medical Research Council dyspnoea scale  $\geq 4$ ) • Diagnosed CHF patients Exclusion Criteria: • Neuromuscular or neurological disorders • Severe arthrosis or other musculoskeletal limitations • Implanted cardiac pacemaker • Knee osteoarthritis, Rheumatoid arthritis • Any inflammation in knee • Peripheral Neuropathy • Diagnosis of cancer • Acute exacerbation requiring hospital admission or systemic corticosteroids in the preceding 4 weeks.

##### Intervention groups

Group A will receive Neuro Mnsular Electrical Stimulation therapy, and Group B will undergo traditional strength training and NMES, with both groups following standardized protocols for the same duration and frequency of sessions.

##### Main outcome variables

Maximal Voluntary Contraction (MVC) on the quadriceps muscles of patients by using a dynamometer. Left Ventricular Ejection Fraction (LVEF) will be assessed through echocardiography. The Rate of Perceived Exertion (RPE). Functional Capacity Evaluation (FCE) will be assessed by 6-min Walk Test (6MWT).

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191117045462N22**

Registration date: **2024-08-06, 1403/05/16**

Registration timing: **prospective**

Last update: **2024-08-06, 1403/05/16**

Update count: **0**

##### Registration date

2024-08-06, 1403/05/16

##### Registrant information

##### Name

Wajeeha Zia

##### Name of organization / entity

Riphah International University

##### Country

Pakistan

##### Phone

+92 42 35126110

##### Email address

wajeeha\_z@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-08-15, 1403/05/25

##### Expected recruitment end date

2024-12-15, 1403/09/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effects of Quadriceps muscle activation with Neuromuscular Electrical Stimulation in patients with Congestive heart failure

## Public title

Effects of Quadriceps muscle activation with Neuromuscular Electrical Stimulation in patients with Congestive heart failure

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

45-60 years of age Congestive Heart Failure patients Forced expiratory volume in 1 second (FEV1) less than 50% predicted Incapacitating breathlessness (Medical Research Council dyspnoea scale  $\geq 4$ ) Diagnosed CHF patients

### Exclusion criteria:

Neuromuscular or neurological disorders Severe arthrosis or other musculoskeletal limitations Implanted cardiac pacemaker Knee osteoarthritis, Rheumatoid arthritis Any inflammation in knee • Peripheral Neuropathy Diagnosis of cancer Acute exacerbation requiring hospital admission or systemic corticosteroids in the preceding 4 weeks .

## Age

From **45 years** old to **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **54**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Participants will be randomly allocated to Group A or Group B through a simple randomization process using sealed opaque envelopes labeled as 0 for Group A and 1 for Group B.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The study will be double blinded. The assessor physiotherapist and the patient both will be double blinded. Although the consent form will be taken from the patient. But the patient will not be aware of the study. Assessor physiotherapist will be involved in the study. He will access the patient by defined outcome measure tools before the start of the study at the end.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Riphah college of rehabilitation & Allied Health Sciences

##### Street address

25 Raza Saeed Rd, Bhabra Block M Gulberg III, Lahore, Punjab 25-M Block, Lahore

##### City

Lahore

##### Postal code

54660

#### Approval date

2024-07-16, 1403/04/26

#### Ethics committee reference number

RCS&AHS/REC/MS-CPPT

## Health conditions studied

### 1

#### Description of health condition studied

Congestive Heart Failure

#### ICD-10 code

#### ICD-10 code description

Systolic (congestive) heart failure

## Primary outcomes

### 1

#### Description

Maximal Voluntary Contraction (MVC)

#### Timepoint

Pre- Post Treatment

#### Method of measurement

Dynamometer

### 2

#### Description

Left Ventricular Ejection Fraction (LVEF)

#### Timepoint

Pre- Post Treatment

#### Method of measurement

Echocardiography

### 3

#### Description

The intensity of exercise

#### Timepoint

Pre- Post Treatment

#### Method of measurement

The Rate of Perceived Exertion (RPE)

#### 4

##### **Description**

Functional Capacity

##### **Timepoint**

Pre- Post Treatment

##### **Method of measurement**

6-min Walk Test (6MWT)

#### **Secondary outcomes**

empty

#### **Intervention groups**

##### 1

##### **Description**

Intervention group: Neuromuscular Electrical Stimulation (NMES); For NMES therapy, electrodes will be strategically placed on the quadriceps muscles, with sessions lasting 30 minutes, conducted three times per week. The NMES intensity will be adjusted to achieve strong but comfortable contractions during each session.

##### **Category**

Rehabilitation

##### 2

##### **Description**

Control group: Participants will participate in a comprehensive strength training regimen that will undergo Neuro Muscular Electrical Stimulation and traditional strength training.

##### **Category**

Rehabilitation

#### **Recruitment centers**

##### 1

##### **Recruitment center**

**Name of recruitment center**  
Gulab Devi Hospital, Lahore.

**Full name of responsible person**  
Maheera Khalid

**Street address**  
F8MV+5HW, Ferozpur Rd

**City**  
Lahore

**Postal code**  
05307

**Phone**  
+92 337 7407559

**Email**  
maheerakhalid0899@gmail.com

#### **Sponsors / Funding sources**

##### 1

##### **Sponsor**

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

Riphah International University

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

Wajeeha Zia

##### **Street address**

25 Raza Saeed Rd, Bhabra Block M Gulberg III,  
Lahore, Punjab 25-M Block, Lahore

##### **City**

Lahore

##### **Postal code**

54660

##### **Phone**

+92 42 111 747 424

##### **Email**

wajeeha\_z@yahoo.com

##### **Grant name**

Nil

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Riphah International University

##### **Proportion provided by this source**

15

##### **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**

Riphah International University

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

Maheera Khalid

##### **Position**

Student

##### **Latest degree**

Master

##### **Other areas of specialty/work**

Physiotherapy

##### **Street address**

Royal Garden Harbanspura, Lahore

##### **City**

Lahore

##### **Province**

Punjab

##### **Postal code**

54850

##### **Phone**

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##### **Email**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Wajeeha Zia

**Position**

Senior Lecturer

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for updating data

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**Name of organization / entity**

Riphah International University

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Maheera Khalid

**Position**

Student

**Latest degree**

Master

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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**

There is no further information.

**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**

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