

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 ≥ 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 Muscular 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 ≥ 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. Accessor 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, Ferozepur Rd

City

Lahore

Postal code

05307

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+92 337 7407559

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maheerakhalid0899@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Riphah International University

Full name of responsible person

Wajeeha Zia

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

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Phone

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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

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Royal Garden Harbanspura, Lahore

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Riphah International University

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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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