Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Mnuscular 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
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+92 42 35126110
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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
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05307
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Riphah International University
Full name of responsible person
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25 Raza Saeed Rd, Bhabra Block M Gulberg III, Lahore, Punjab 25-M Block, Lahore
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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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Person responsible for scientific inquiries

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Latest degree
Ph.D.

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Physiotherapy

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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