

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The effect of pulmonary rehabilitation, inspiratory muscle training and therapeutic exercise training on the phrenic nerve conduction study and diaphragm muscle ultrasound findings in patients with diaphragm paralysis

Protocol summary

Study aim

The effect of pulmonary rehabilitation, inspiratory muscle training and therapeutic exercise training on the phrenic nerve conduction study and diaphragm muscle ultrasound findings in patients with diaphragm paralysis

Design

Clinical trial without control group, not blinded, no randomization, phase 3, per 30 patients.

Settings and conduct

First, the Pulmonary Function Test is performed. The Nerve Conduction Study of the phrenic nerve is then performed. Diaphragm muscle ultrasound is performed. Quality of life questionnaire and six-minute walk test are also performed at the beginning of the study. Pulmonary rehabilitation is taught in the form of training exercises and aerobic and resistance exercises of the limbs to be done at home. Inspiratory muscle training is delivered to the patient and he is taught how to work with this device. The next visits of patients will be three and six months later. In order to prevent human error and ensure the correctness of the exercises, follow-up of patients through telephone calls is on the agenda. At the visit, after six months, all the actions that were initially taken will be reviewed and recorded again.

Participants/Inclusion and exclusion criteria

Inclusion criteria include a diaphragmatic hernia visible on a chest x-ray or a lung CT scan, age over 12 years. Exclusion criteria include the individual's dissatisfaction with participation in the study and the patient's inability.

Intervention groups

In the control group, patients with unilateral diaphragmatic dysfunction, pulmonary function test, and nerve conduction studies are performed. The next steps are diaphragm ultrasound, completing a quality of life questionnaire, and a 6-minute walk test. In the intervention group, patients use the inspiratory muscle

training device in addition to the measures performed in the control group.

Main outcome variables

Amplitude and latency of phrenic nerve

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210813052172N1**

Registration date: **2022-02-08, 1400/11/19**

Registration timing: **prospective**

Last update: **2022-02-08, 1400/11/19**

Update count: **0**

Registration date

2022-02-08, 1400/11/19

Registrant information

Name

Masoumeh ZoghAli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3662 4225

Email address

masoumezoghali@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2023-03-21, 1402/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
The effect of pulmonary rehabilitation, inspiratory muscle training and therapeutic exercise training on the phrenic nerve conduction study and diaphragm muscle ultrasound findings in patients with diaphragm paralysis

Public title
The effect of pulmonary rehabilitation, inspiratory muscle training and therapeutic exercise training in patients with diaphragmdysfunction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Elevation of the diaphragm evident on chest X-ray
Elevation of the diaphragm evident on CT scan of the lung
Age over 12 years
Exclusion criteria:
Individual dissatisfaction with participation in the study
The patient's inability to perform the desired exercises

Age
From **12 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
N/A

Randomization description

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
Ethics Committee in Research Shahid Beheshti University

Street address
Masih Daneshvari Hospital, Darabad
City
Tehran
Province
Tehran
Postal code
1956944413

Approval date
2021-11-03, 1400/08/12
Ethics committee reference number
IR.SBMU.NRITLD.REC.1400.060

Health conditions studied

1

Description of health condition studied
Patients with diaphragm paralysis
ICD-10 code
J98.6
ICD-10 code description
Disorders of diaphragm

Primary outcomes

1

Description
Phrenic nerve amplitude
Timepoint
Before training, three and six months later
Method of measurement
Electromyogram and nerve conduction study

2

Description
Phrenic nerve latency
Timepoint
Before training, three and six months later
Method of measurement
Electromyogram and nerve conduction study

3

Description
Diaphragm muscle thickness
Timepoint
Before training, three and six months later
Method of measurement
Ultrasound device

4

Description
Diaphragm movement speed
Timepoint
Before training, three and six months later
Method of measurement
six minute walk test

5

Description

Forced Expiratory Volume, Forced Expiratory Volume in First Second

Timepoint

Before training, three and six months later

Method of measurement

Spirometry

6

Description

Maximum expiratory pressure and maximum inspiratory pressure

Timepoint

Before training, three and six months later

Method of measurement

Body box

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In patients with unilateral dysfunction of the diaphragm, a pulmonary function test and then nerve conduction study of the phrenic nerve is performed. The next steps are diaphragm muscle ultrasound, completing a quality of life questionnaire, and a six-minute walk test. Patients use the inspiratory muscle training device for 6 months.

Category

Rehabilitation

2

Description

Control group: In patients with unilateral dysfunction of the diaphragm, a pulmonary function test and then nerve conduction study of the phrenic nerve is performed. The next steps are diaphragm muscle ultrasound, completing a quality of life questionnaire, and a six-minute walk test.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Masoume Zoghali

Street address

Shahid Bahonar St., Darabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway

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198396411

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masoume Zoghali

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Researcher

Latest degree

Master

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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