Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 3000
Email
masoumezoghali@sbmu.ac.ir

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
City
Tehran
Province
Tehran
Postal code
198396411
Phone
+98 21 2243 9781
Email
Mpajouhesh@sbmu.ac.ir
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

Street address
Shahid Bahonar St., Darabad

City
Tehran

Province
Tehran

Postal code
1956944413

Phone
+98 21 2610 5050

Email
masoumezoghali@sbmu.ac.ir

Person responsible for scientific 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

Street address
Shahid Bahonar St., Darabad

City
Tehran

Province
Tehran

Postal code
1956944413

Phone
+98 21 2610 5050

Email
masoumexoghali@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Reyhaneh Zahiri

Position
Researcher

Latest degree
Master

Other areas of specialty/work
Biotechnology

Street address
Shahid Bahonar St., Darabad

City
Tehran

Province
Tehran

Postal code
1956944413

Phone
+98 21 2610 5050

Email
zahirireyhane@gmail.com

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