

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

##### **City**

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#### **Province**

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#### **Postal code**

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#### **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

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**Person responsible for scientific inquiries**

**Contact**

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Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Masoume Zoghali

**Position**

Assistant Professor

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Specialist

**Other areas of specialty/work**

Physical Medicine

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**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

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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