Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Inspiratory muscle training compared with diaphragmatic breathing in respiratory parameters and quality of life, in ALS patients

Protocol summary

Study aim

Determining the effect of using the Inspiratory muscle training in comparison with diaphragmatic exercises in respiratory indicators and quality of life of patients with amyotrophic lateral sclerosis

Design

A clinical trial with a control group, randomized by block method, without blinding, on 22 patients

Settings and conduct

Patients with amyotrophic lateral sclerosis referred to Masih Daneshvari Hospital in Tehran before the start of the study underwent a 6-minute walking test, maximum respiratory pressure determination, and completion of a quality of life questionnaire. These assessments were compared after 8 weeks of treatment on the intervention and control group.

Participants/Inclusion and exclusion criteria

Conditions for study: Male and female patients with amyotrophic lateral sclerosis at the discretion of the physician, ability to perform exercises, maximal inspiratory pressure less than 60 cmH2O, no history of surgery in the last 12 months, no severe osteoporosis, Borg Scale less than 6 The criteria for leaving the study include the patient's reluctance, the patient's inability to participate in the regular training program and the intervention procedure or the use of non-invasive ventilation

Intervention groups

In the control group, patients underwent diaphragmatic exercises and chest opening exercises. In the intervention group, in addition to standard therapies, patients used an inspiratory muscle training device.

Main outcome variables

Maximum inspiratory pressure; Maximum expiratory pressure; Carbon dioxide pressure, muscle strength index; forced expiratory volume; Total lung capacity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200611047727N2**
Registration date: **2020-07-07, 1399/04/17**
Registration timing: **retrospective**

Last update: **2020-07-07, 1399/04/17**
Update count: **0**

Registration date

2020-07-07, 1399/04/17

Registrant information

Name

Maryam Sadat Mirenayat

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2610 5050

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

2019-04-21, 1398/02/01

Actual recruitment end date

2019-09-23, 1398/07/01

Trial completion date

2019-09-23, 1398/07/01

Scientific title

The effect of Inspiratory muscle training compared with diaphragmatic breathing in respiratory parameters and quality of life, in ALS patients

Public title
Investigation of IMT effect in ALS patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Male and female patients with amyotrophic lateral sclerosis were diagnosed by a physician Ability to do exercises Maximal inspiratory pressure less than 60 cmH2O No history of surgery in the last 12 months No severe osteoporosis Shortness of breath less than 6 (Borg scale less than 6)
Exclusion criteria:
Physical or mental disability of the patient to perform exercises Perform an intervention procedure or use non-invasive ventilation Patient dissatisfaction
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **22**
Actual sample size reached: **22**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization Method: Blocked Randomization Unit: Individual Randomization Tool: Number Table Using 2 therapeutic blocks (11 patients in each block), patients were randomly placed in two separate blocks based on the patient's code and file number. Patients in these blocks were randomly transferred and a balanced randomized list of the two treatment groups was obtained. In the first group of patients, in addition to standard treatments, controlled exercise included diaphragmatic strengthening exercises and chest opening exercises. In the second group of patients, in addition to the treatments applied for the control group (the first group), they were also treated with an inspiratory muscle training device.
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 of Shahid Beheshti University
Street address
Shahid Arabi St., Yemen St.,Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2018-12-04, 1397/09/13
Ethics committee reference number
IR.SBMU.NRITLD.REC.1397.073

Health conditions studied

1

Description of health condition studied
Amyotrophic lateral sclerosis
ICD-10 code
G12.21
ICD-10 code description
Amyotrophic lateral sclerosis

Primary outcomes

1

Description
Quality of Life
Timepoint
Before the study and 8 weeks after the start of treatment
Method of measurement
Quality of Life Questionnaire

Secondary outcomes

1

Description
Maximum inspiratory pressure
Timepoint
Before the start of the study and 8 weeks after the treatment
Method of measurement
Spirometry

2

Description
Maximum expiratory pressure
Timepoint
Before the start of the study and 8 weeks after the treatment

Method of measurement
Spirometry

Intervention groups

1

Description
Control group: In addition to standard treatments, patients undergo controlled exercise therapy, including diaphragmatic exercises and chest opening exercises. The duration of these exercises is 30 minutes. These exercises are performed for 8 weeks and twice a day
Category
Rehabilitation

2

Description
Intervention group: In addition to standardized treatments and controlled exercise therapy (similar to the control group), patients use inspiratory muscle training device in a controlled manner. These exercises are repeated for 8 weeks and twice a day.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Melika Valizadeh
Street address
Masih daneshvari Hospital, Shahid Bahonar St., Darabad, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Maryam Mirenayat
Position
Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Clinical trial data will be published as an article
When the data will become available and for how long
Start access 6 months after printing results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Related scientific research
From where data/document is obtainable
Masih Daneshvari Hospital, Chronic Respiratory Diseases Research Center, Tehran
What processes are involved for a request to access data/document
Provide the initial file of the approved research plan
Comments