

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Inspiratory muscle training in quality of life, aerobic capacity and pulmonary functional index in patients with COVID-19 in Masih-Daneshvari hospital

Protocol summary

Study aim

The Effect of Inspiratory muscle training in quality of life, aerobic capacity and pulmonary functional index in patients with COVID-19 in Masih-Daneshvari hospital

Design

control group, parallel, randomized groups, Simple randomization method

Settings and conduct

All patients who meet the entry criteria and have completed the consent form for participation in the project are invited to take the test. Tests include: Complete an individual information questionnaire; Quality of Life Questionnaire ; MMRC shortness of breath index; 6MWT; PIMAX and PEMAX tests After the tests, patients are randomly divided into two groups. The first group includes breathing exercises, including diaphragmatic breathing exercises, bud lip breathing, and limb exercises, and the exercise brochure is given to patients. In the second group, in addition to the above exercises, patients are also taught how to use the IMT device. Patients in both groups do the exercises for 4 weeks. (Twice a day) After 4 weeks, patients are called to the hospital for re-evaluation.

Participants/Inclusion and exclusion criteria

age: 20-60; PCR Test (Rt: - PCR); Negative Hospital discharge; Lack of oxygen dependence; 10 days has passed since the quarantine ; Absence of any underlying disease; PIMAX less than 60%

Intervention groups

inspiratory muscle training

Main outcome variables

6 minute walking distance; strength index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200611047727N1**

Registration date: **2020-06-24, 1399/04/04**

Registration timing: **prospective**

Last update: **2020-06-24, 1399/04/04**

Update count: **0**

Registration date

2020-06-24, 1399/04/04

Registrant information

Name

Maryam Sadat Mirenayat

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2610 5050

Email address

mirenayat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Inspiratory muscle training in quality of life, aerobic capacity and pulmonary functional index in

patients with COVID-19 in Masih-Daneshvari hospital

Public title

The Effect of Inspiratory muscle training in patients with COVID-19

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All male and female patients who have undergone the course of Qovid 19 disease and have referred to the follow-up clinic of Masih Daneshvari Hospital. The age of the clients is between 20 and 60 years Negative PCR Test (Rt: - PCR) Hospital discharge according to the national discharge protocol Lack of oxygen dependence The time between one week and 10 days has passed since the quarantine period Absence of any underlying disease including COPD, CHF and neuromuscular disease or motor disorders PIMAX less than 60%

Exclusion criteria:

With any of the experts or unwillingness to continue participating in the project

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: simple Unit of randomization : individual Tools used in randomization : table of random numbers Included patients, in a simple randomized evaluation using even and odd numbers, would get codes for each treatment group. In case of odd numbers, the patient would be enrolled in the group one to receive high flow oxygenation at the first stage and following a washout period, take noninvasive ventilation. On the other hand, patients gotten even numbers would receive noninvasive ventilation for the first stage. Then, after a washout period, high oxygen therapy would be prescribed.

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 Shahidbeheshti University of Medical Sciences

Street address

Masih Daneshvari Hospital, Darabad, Bahonar Ave, Tehran Town, Iran

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2020-04-30, 1399/02/11

Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.088

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Strenght Index

Timepoint

The first day and four weeks later

Method of measurement

Inspiratory muscle training

Secondary outcomes

1

Description

Walking distance test six minutes

Timepoint

At the beginning of the study (before the intervention begins) and four weeks later

Method of measurement

Strenght Index

2

Description

SF12 scale

Timepoint

At the beginning of the study (before the intervention begins) and four weeks later

Method of measurement
questionnaire

Intervention groups

1

Description

Intervention group: In this group, patients are taught to perform breathing exercises for four weeks with the help of the respiratory muscle strengthening device. This device is designed in such a way that the patient puts a filter on his mouth. He takes a deep breath and tries to make the most of his abdominal muscles. The patient performs 30 repetitions with the device twice a day. Each week, the intensity of the device increases by one degree. Variables are measured on the first day and after four weeks.

Category

Rehabilitation

2

Description

Common treatment: This group teaches patients regular breathing exercises, including bud breathing, diaphragmatic breathing, and deep breathing, and provides exercise brochures to patients. They are asked to practice for four weeks each day. Do it twice and the intervention variables are measured on the first day and after the fourth week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Maryam Mirenayat

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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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

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Physiology

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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

مرکز تحقیقات بیماری های مزمن تنفسی بیمارستان مسیح دانشوری
تهران

What processes are involved for a request to access data/document

Provide the initial file of the approved research plan

Comments