Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 quarantin ;Absence of any underlying disease; PIMAX less than 60%

Intervention groups
inspraitory muscle training

Main outcome variables
6 minute walking distance;strenght 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)

Phone
+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 got 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
Inspratory muscle traning

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2712 2541

Email

MirenayaT_M@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

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

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2712 2541

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

Maryam Mirenayat

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

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

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2610 5050

Email
MirenayaT_M@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Atefeh Fakharian
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Tehran
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2610 5050
Email
fakharian_2005@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Saba Karimzade
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Physiology
Street address
Masih Daneshvari Hospital, Darabad, Bahonar Ave, Tehran Town, Iran
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 2541
Email
sabakarimzade@yahoo.com

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