Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of the integrated drug- incentive spirometry therapy with drug therapy alone on recovery and mortality of patients admitted to hospital with Covid 19

Protocol summary

Study aim

Evaluation of the effectiveness of integrated drug therapy and respiratory training with incentive spirometer on mortality and recovery rates of adult patients admitted to hospital with Covid 19.

Design

A clinical trial with the control group, with parallel groups, three-way blind, randomized, phase 3 on 160 patients. Randomization will be performed using the rand function of Excel software.

Settings and conduct

Participants are among 19 patients admitted to the non-intensive care unit of Imam Hussein Hospital in Tehran. Patients will be divided into intervention and control groups. Both study groups receive the same drug and non-drug treatments according to the latest published version of the national protocol. The case group will perform breathing exercises according to the study protocol. By assigning a dedicated code to participants, data collectors, treatment teams, patients, and analysts are blinded to group assignments.

Participants/Inclusion and exclusion criteria

Patients with definite Covid19, greater equal 18 years old with peripheral oxygen levels less than 94% who do not require intensive care, no pregnancy, and no history of chronic lung or heart disease.

Intervention groups

Eligible patients will be divided into two groups of 80, control and intervention. Both groups receive the same drug treatment according to the declared protocol. In addition, the intervention group was asked to perform breathing exercises with an encouraging spirometer on a daily basis.

Main outcome variables

-Clinical recovery rate -Severity Dyspnea based on Modified Borg 0-10 scale (MBS) -Blood pressure; Heart rate; Respiratory rate; Symptoms of respiratory distress in the form of intercostal and sternal retraction and use of respiratory sub-muscles; O2 sat (pulse oximetry) in two modes with/without (oxygen therapy)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201012049010N2**
Registration date: **2022-03-04, 1400/12/13**
Registration timing: **retrospective**

Last update: **2022-03-04, 1400/12/13**
Update count: **0**

Registration date

2022-03-04, 1400/12/13

Registrant information

Name

Mohammad Bargahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-16, 1400/05/25

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

2021-08-19, 1400/05/28

Actual recruitment end date
2021-10-21, 1400/07/29
Trial completion date
2022-02-04, 1400/11/15

Scientific title
Comparison of the effect of the integrated drug-incentive spirometry therapy with drug therapy alone on recovery and mortality of patients admitted to hospital with Covid 19

Public title
Efficacy and Safety of Respiratory Exercises with Incentive Spirometry in Hospitalized Adult Patients with SARS-CoV-2
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Older age equals 18 years Patients with Covid 19 (based on diagnostic methods of the latest published version of the National Protocol) Need to be admitted to a non-intensive care unit Hospitalization in the last 6 hours
Exclusion criteria:
Any case of CNS disorder that interferes with patient communication and educability Need to be admitted to the intensive care unit at the time of enrollment history of lung disease sPo2<94% (at room air) Participation in any other clinical trial of an experimental treatment for COVID-19 pregnant woman or man who his spouse is pregnant history of CHF Requiring mechanical ventilation at screening Evidence of multi-organ failure Recent of ACS no willingness for enrollment
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **160**
Actual sample size reached: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method in this study was based on Simple randomization (random numbers table). To create a random list in Excel software, 160 samples (two identical groups of 80) were considered in one column, then the RAND function was assigned. In the end, the samples were sorted from low to high. On a daily basis, eligible patients were assigned by the registrants based on the embedded list in two groups: A) control and B) intervention. Registrants, outcome assessors, and the relevant health care team were not aware of the randomization process.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Eligible patients were divided into two groups by a two-person group of researchers based on a designed table. For one of the patients, a data collection form with a special code will be determined at the time of enrollment. The data were collected by a separate team of collectors on a daily basis and recorded in a designed online data sheet. Health care providers and the treatment team were also unaware of the allocation of patients to either group. The collected data will be statistically analyzed by the analysis group in groups A and B without group-specific labels.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Imam Hussein Hosp, Shahid Madani St, Teharan
City
Tehran
Province
Tehran
Postal code
1617763141
Approval date
2021-10-31, 1400/08/09
Ethics committee reference number
IR.SBMU.RETECH.REC.1400.519

Health conditions studied

1

Description of health condition studied
Covid19
ICD-10 code
U07.1 + J1
ICD-10 code description
مواردتائید شده کووید 19 با بیماری تنفسی (پنومونی ویروسی) و/یا (علایم و نشانه های بیماری تنفسی(تنگی نفس ، سرفه

Primary outcomes

1

Description

Clinical recovery rate

Timepoint

Daily until discharge from the hospital

Method of measurement

No shortness of breath (by patients) + Larger SpO2 equal to 93 (no oxygen uptake) + lower temperature equal to 37.5 ° C for 48 hours.

2

Description

Respiratory rate

Timepoint

The first day before the intervention and daily for 5 days or until discharge, whichever is earlier

Method of measurement

Number of breaths per 1 minute

3

Description

Peripheral blood oxygen saturation in oxygen therapy

Timepoint

The first day before the intervention and daily for 5 days or discharge, whichever is earlier

Method of measurement

Percentage of oxygen after 2 minutes with finger pulse oximeter in 5 minutes apart from oxygen while sitting on the bed

4

Description

Percentage of peripheral blood oxygen saturation in the absence of oxygen therapy

Timepoint

The first day before the intervention and daily for 5 days or discharge, whichever is earlier

Method of measurement

Percentage of oxygen after 2 minutes with a finger pulse oximeter while sitting on the bed

5

Description

Intravenous carbon dioxide content

Timepoint

The first day of hospitalization and the fifth day or time of discharge, whichever is earlier

Method of measurement

According to the VBG report

6

Description

Intravenous oxygen level

Timepoint

The first day of hospitalization and the fifth day or time of discharge, whichever is earlier

Method of measurement

According to the VBG report

7

Description

Intravenous bicarbonate

Timepoint

The first day of hospitalization and the fifth day or time of discharge, whichever is earlier

Method of measurement

According to the VBG report

8

Description

Intravenous blood pH

Timepoint

The first day of hospitalization and the fifth day or time of discharge, whichever is earlier

Method of measurement

According to the VBG report

9

Description

Severity of dyspnea

Timepoint

The first day before the intervention and daily for 5 days or discharge, whichever is earlier

Method of measurement

Based on Modified Borg Standard Questionnaire 0-10 scale (MBS)

10

Description

Blood pressure

Timepoint

The first day before the intervention and daily for 5 days or discharge, whichever is earlier

Method of measurement

With the same standard sphygmomanometer cuff while the patient is sitting on the bed for 10 minutes

11

Description

Sex

Timepoint

the first day

Method of measurement

Being male or female

12

Description

Stress level

Timepoint

The first day before the intervention and daily for 5 days or discharge, whichever is earlier

Method of measurement

Based on the standard Zung Self-Rating Anxiety Scale (SAS)

13

Description
Duration of hospitalization
Timepoint
From the first day of hospitalization until discharge
Method of measurement
Number of days elapsed until discharge

Secondary outcomes

1

Description
One-month mortality rate for any reason
Timepoint
One month after enrollment
Method of measurement
telephone follow-up

2

Description
3-month mortality rate for any reason
Timepoint
3 months after enrollment
Method of measurement
telephone follow-up

3

Description
The need for intubation
Timepoint
Until discharge from the hospital
Method of measurement
Number of intubated patients based on the opinion of the relevant treatment team

4

Description
The need for hospitalization in the intensive care unit
Timepoint
Until discharge from the hospital
Method of measurement
Number of patients admitted to the intensive care unit based on the opinion of the relevant treatment team

5

Description
Maximum exhaled exhaust air pressure in the first second
Timepoint
3 months after the time of enrollment
Method of measurement
According to spirometry reports

6

Description
Maximum amount of exhaust air
Timepoint
3 months after the time of enrollment
Method of measurement
According to spirometry reports

7

Description
Ratio of exhaust air loss from the first second to the total
Timepoint
3 months after the time of enrollment
Method of measurement
According to spirometry reports

8

Description
Overall carbon monoxide emission capacity
Timepoint
3 months after the time of enrollment
Method of measurement
According to spirometry reports

9

Description
Mileage in 3 minutes
Timepoint
3 months after the time of enrollment
Method of measurement
Based on standard 3-minute walk distance test (6MWD)

Intervention groups

1

Description
Intervention group: Patients in this group (from the day of admission to the study) were given the same in addition to pharmacological and non-pharmacological treatments. After each training session, the patients in the intervention group were asked to intervene after a deep breath for 2 to 5 seconds and confinement. Breathe for 1 second, begin to exhale deeply in the spirometer, encourage each time they can take action, then wait for rest until the patient feels the need, then repeat this breathing exercise 4 more times with the same quality. Will repeat. If the patient receives oxygen through the mouth mask, he or she will receive oxygen through the nasal mask during breathing exercises. This group was also asked to continue the same treatment for the given exercise in case of discharge from the hospital for up to 3 months.
Category
Treatment - Devices

2

Description
Control group: Patients in this group did not receive any additional intervention and received the same drug and non-drug treatments as the intervention group, based on the opinion of the relevant treatment team according to

the latest published version of the national protocol.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hussein Hospital

Full name of responsible person
Naser Parvaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Mohammad Bargahi

Position
General practitioner

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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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
All collected data can be subscribed in CSV format after identifying the participants. And videos taken from patients during breathing exercises can also be shared if they are satisfied.

When the data will become available and for how long
Immediately after publishing the article

To whom data/document is available
All researchers and individuals working in academic and scientific institutions

Under which criteria data/document could be used
For all scientific and therapeutic uses

From where data/document is obtainable
Email the corresponding author and the first author of the relevant article

What processes are involved for a request to access data/document
After receiving the email, the request will be answered in coordination with the responsible team, and mentioning the source is mandatory

Comments