Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of respiratory muscle training and N-acetyl cysteine supplementation on hematological profiles, blood gases, some inflammatory markers, mood, sleep quality, and sleep quality in hospitalized pulmonary patients with corona virus infection.

Protocol summary

Study aim

,Examining the average changes of blood gases, blood parameters, sugar, urea, albumin, bilirubin, creatinine, liver enzymes and blood cells, lactate dehydrogenase enzyme, blood minerals, inflammatory marker CRP, acute phase positive inflammatory proteins D-Dimer , ferritin, percentage of lung involvement with infection, mood state, sleep quality of hospitalized patients with COVID-19 in the intervention groups and comparing it with the control group

Design

Clinical trial with control group, single blind, randomized, phase 3 on 104 patients. Randomization will be done using rand function of Excel software

Settings and conduct

104 patients with covid-19 hospitalized in the non-special care department of Firouzgar Hospital are randomly divided into 4 groups. All four study groups receive the same drug and non-drug treatments according to the latest published version of the national protocol. The breathing exercise intervention group according to will conduct a study protocol. By assigning a specific code to the participants, blinding is done.

Participants/Inclusion and exclusion criteria

Patients with confirmed covid-19 in non-critical conditions and not hospitalized in the special care department in the age range of 18 to 65 years, as well as the absence of pregnancy and breastfeeding, anti-depressant and anxiety medications, and the absence of underlying diseases

Intervention groups

Group 1: Respiratory muscle training Group 2: N-acetyl cysteine group Group 3: N-acetylcysteine group + respiratory muscles Group 4: control group(by receiving a placebo)

Main outcome variables

Changes in blood gases, blood parameters, sugar, urea, albumin, bilirubin, creatinine, liver enzymes and blood cells, lactate dehydrogenase enzyme, blood minerals, inflammatory marker CRP, acute positive inflammatory phase proteins D-Dimer, ferritin The percentage of lung involvement with infection, mood, sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220724055541N1**
Registration date: **2022-08-30, 1401/06/08**
Registration timing: **prospective**

Last update: **2022-08-30, 1401/06/08**
Update count: **0**

Registration date

2022-08-30, 1401/06/08

Registrant information

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shadmehr Mirdar Harijani

Name of organization / entity
University of Mazandaran

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-09-02, 1401/06/11
Expected recruitment end date
2022-11-27, 1401/09/06
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of respiratory muscle training and N-acetyl cysteine supplementation on hematological profiles, blood gases, some inflammatory markers, mood, sleep quality, and sleep quality in hospitalized pulmonary patients with corona virus infection.

Public title
The effect of respiratory muscle training and N-acetyl cysteine supplementation on hematological profile, blood gases, some inflammatory markers, mood, sleep quality and lung scan
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to cooperate with the plan 18 to 65 years old Patients with COVID-19 whose disease has been fully confirmed through complete medical examination, pathology and laboratory information Patients with COVID-19 in non-critical conditions and not hospitalized in the intensive care unit
Exclusion criteria:
smoking alcohol consumption Pregnancy and breastfeeding People who, in addition to COVID-19, have other diseases, such as severe kidney, liver, thyroid and parathyroid, glandular, gastrointestinal diseases, and heart and cancer patients.
Age
From **18 years** old to **65 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: **104**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of randomization in this study will be based on the simple randomization method (table of random numbers). By using Random Allocation software and in order to create a random list in Excel software, 104 samples (four identical groups of 26) will be considered in one column, at the end the samples will be sorted from low to high. Also, on a daily basis, patients eligible to enter the study will fill out the FFQ questionnaire, by the registrant based on the list embedded in four groups of 26 people A) control group and B) incentive spirometry group C) N-acetylcysteine group D) Incentive spirometry group + N-acetylcysteine; Allocation will be random. Enrollees, outcome assessors and the relevant healthcare team will not be aware of the randomisation process are team will not be aware of the randomisation process.
Blinding (investigator's opinion)
Single blinded
Blinding description
Eligible patients will be randomly divided into four specified groups based on the table designed by the researcher. For each patient, a data collection form with a specific code will be determined at the time of entering the study. All patients will enter the study with prior information and informed consent. None of the participants will know about the allocation of groups and The control group will receive a placebo in the same form as the intervention group. The relevant data will be collected by a separate team of collectors and recorded in the designed Data Sheet. Health care providers and the relevant treatment team will also be unaware of the assignment of patients to each of the four groups. Finally, the collected data will be statistically analyzed by the analysis group in four groups A, B, C and D, without the specific label of the groups.
Placebo
Used
Assignment
Factorial
Other design features
In addition to the interventions performed in this study, FFQ, sleep, stress and anxiety questionnaires and physical activity will also be used.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee University of Mazandaran
Street address
Faculty of Physical Education and Sports Sciences- University Boulevard - Mazandaran University Campus -- Shahid Beheshti Street - Shahid Zulfiqari Boulevard- Babolsar
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Approval date
2022-01-26, 1400/11/06

Ethics committee reference number
IR.UMZ.REC.1401.001

Health conditions studied

1

Description of health condition studied
Corona virus
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
The percentage of changes in lung involvement
Timepoint
Before the intervention and 4 weeks after the intervention
Method of measurement
Lung scan

2

Description
state of mind
Timepoint
Before the intervention, 4 weeks after the intervention and 2 months after the intervention
Method of measurement
DASS 21 question questionnaire

Secondary outcomes

1

Description
Hematological profile
Timepoint
Before the intervention and 4 weeks after the intervention
Method of measurement
Biochemical analyses

2

Description
Blood gasesHematological profile
Timepoint
Before the intervention and 4 weeks after the intervention
Method of measurement
Biochemical analyses

3

Description
Inflammatory markers
Timepoint
Before the intervention and 4 weeks after the intervention
Method of measurement
Biochemical analyses

4

Description
sleep quality
Timepoint
Before the intervention, 4 weeks after the intervention and 2 months after the intervention
Method of measurement
Pittsburgh Sleep Quality Questionnaire (PSQI)

Intervention groups

1

Description
The first intervention group: 1000 mg of N-acetylcysteine by injection twice a day every 12 hours for two weeks as an IV and in the continuation of the intervention two weeks after discharge also at home four effervescent tablets of 500 mg of N-acetylcysteine twice in The day will be available to patients.
Category
Treatment - Drugs

2

Description
For four weeks, patients will use diaphragmatic breathing exercise and incentive spirometer every day according to the researcher's training. According to religion, the patient will lie on his back and a pillow will be placed under his head and a pillow under his knees, and then one hand will be placed on his chest and the other on his stomach. He will breathe deeply through his nose until his chest and stomach are large and full. and then the air will slowly come out of the mouth. This exercise will be done for one minute and then the patient will rest for 30 seconds and later the patient will use the incentive spirometry device. The patient will be taught to use the mouthpiece of the device place his mouth and inhale with maximum power and then hold the air in his mouth as much as possible (at least 5 seconds) and then let the air out slowly and do this 10 times and every one minute He will rest for 30 seconds. Exercise with spirometer will last 5 minutes. Exercises should be done 3 times a day (morning, noon and night). These exercises are taught and supervised by a respiratory muscle physiotherapist. Exercises are monitored through pulse. Oximeter and Borg scale are performed, in addition to that, incentive spirometry and Dia breathing exercise pattern are used Fragami will be available to the participants of the experimental group in the form of pamphlets and films.
Category
Rehabilitation

3

Description

The third intervention group: N-acetylcysteine group + respiratory muscles. For four weeks, patients will use diaphragmatic breathing exercise and incentive spirometer every day according to the researcher's training. According to religion, the patient will lie on his back and a pillow will be placed under his head and a pillow under his knees, and then one hand will be placed on his chest and the other on his stomach. He will breathe deeply through his nose until his chest and stomach are large and full. and then the air will slowly come out of the mouth. This exercise will be done for one minute and then the patient will rest for 30 seconds and later the patient will use the incentive spirometry device. The patient will be taught to use the mouthpiece of the device place his mouth and inhale with maximum power and then hold the air in his mouth as much as possible (at least 5 seconds) and then let the air out slowly and do this 10 times and every one minute He will rest for 30 seconds. Exercise with spirometer will last 5 minutes. Exercises should be done 3 times a day (morning, noon and night). These exercises are taught and supervised by a respiratory muscle physiotherapist. Exercises are monitored through pulse. Oximeter and Borg scale are performed, in addition to that, incentive spirometry and Dia breathing exercise pattern are used Fragami in the form of pamphlets and films will be provided to the participants of the experimental group, and at the same time, these people will receive 1000 mg of N-acetylcysteine injected twice a day every 12 hours for two weeks as an IV and in the continuation of the intervention two weeks after discharge. At home, four 500 mg N-acetylcysteine effervescent tablets will be provided to patients four times a day.

Category

Treatment - Drugs

4

Description

Control group: The patients of 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. This group received four 500 mg starch capsules daily. They will take it as a placebo for eight weeks. The placebo will be prepared by Karen Pharmaceutical Company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar Hospital

Full name of responsible person

Mobina Aghajani

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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

University of Mazandaran

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
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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
No - There is not 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
Tehran, all inclusive data (IPD), study protocol, statistical analysis map, informed consent form, clinical study report and data dictionary will be published after the completion of the study. The identity of the participants will not be published
When the data will become available and for how

long

The data will be available immediately after the completion of the project. It will probably be published in 1401.

To whom data/document is available

Scholars working in academic and scientific institutions

Under which criteria data/document could be used

For the development of related sciences

From where data/document is obtainable

Refer to Firouzgar Hospital in Tehran by submitting a letter of introduction

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

Presentation of valid letter from scientific centers

Comments