Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation effects of multimodal rehabilitation on recovery of ICU Acquired weakness following coronavirus infection(COVID-19)

Protocol summary

Study aim
Evaluation effects of multimodal rehabilitation on recovery of ICU Acquired Weakness following COVID-19 infection

Design
Quasi-experimental clinical trial, without control group, without blinding and randomization, on 27 patients

Settings and conduct
All selected patients will be evaluated for 3 weeks after discharge by referring to the sports medicine clinic (located in Imam Khomeini Hospital in Sari). Rehabilitation will be designed as 2 sessions per week (16 sessions) and the duration of each session will be approximately 40 minutes for each patient. Exercises include: Strength exercises, Inspiratory Muscle Training with the KH5 digital Power Breath (Start with a resistance of 30% of Maximal Inspiratory Pressure) and Aerobic exercises using a Stationary Bike and Treadmill (Depending on the patient's Exercise capacity). Gradually increase the intensity of the exercises in proportion to the individual's progress. All sessions will be performed under supervision and the initial examinations will be repeated after the sessions.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Definitive diagnosis of Coronavirus based on Polymerase Chain Reaction Or lung CT Scan ; ICU Acquired Weakness diagnosis (Criteria: Total muscle strength, bilaterally according to Medical Research Council criteria is less than 48 (out of 60 total points) ; Normal consciousness ; History of hospitalization in ICU for more than 48 hours (with/without the need for Mechanical ventilation) Exclusion criteria: Loss of consciousness ; Concurrent Heart disease ; Hypoxia at rest ; Fever Or Acute systemic disease

Intervention groups
Patients with COVID-19 with a history of ICU admission, with Or without Mechanical ventilation, with ICU Acquired Weakness diagnosis

Main outcome variables
Peripheral muscle strength; Respiratory muscle strength; Quality of life

General information

Reason for update
Due to the mismatch between the predicted and realized dates for sample collection

Acronym

IRCT registration information
IRCT registration number: **IRCT20200117046160N2**
Registration date: **2021-08-05, 1400/05/14**
Registration timing: **prospective**

Last update: **2022-04-09, 1401/01/20**
Update count: **1**

Registration date
2021-08-05, 1400/05/14

Registrant information

Name
Hanieh Adib

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-20, 1399/01/01

Expected recruitment end date
2021-09-22, 1400/06/31

Actual recruitment start date
2021-08-06, 1400/05/15

Actual recruitment end date
2022-01-05, 1400/10/15
Trial completion date
2022-03-06, 1400/12/15

Scientific title
Evaluation effects of multimodal rehabilitation on recovery of ICU Acquired weakness following coronavirus infection(COVID-19)

Public title
"Effects of multimodal rehabilitation on recovery of ICU Acquired weakness following COVID-19"
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of Coronavirus based on Polymerase Chain Reaction (PCR) or lung CT Scan and expert opinion Intensive Care Unit Acquired Weakness (ICUAW) diagnosis based on the following criteria: - Total muscle strength points of 6 muscle groups bilaterally (Forearm flexion, wrist extension, Hip flexion, knee extension, Ankle dorsiflexion, Arm abduction) in manual examination according to Medical Research Council(MRC) criteria is less than 48 (out of 60 total points) - Normal consciousness based on Glasgow Coma Scale(GCS) (score 15 out of 15) - Opinion of an Anesthesiologist or Intensive Care Fellowship - History of hospitalization in ICU for more than 48 hours (with and without the need for Mechanical ventilation)
Exclusion criteria:
Loss of consciousness Uncontrolled hypertension means: resting systolic blood pressure> 180 mmHg and / or resting diastolic blood pressure> 110 mmHg Chest pain Uncontrolled sinus tachycardia (> 120 beats / min) or Sinus bradycardia (HR <60) Concurrent heart disease such as: Decompensated heart failure and evidence of Ischemic heart disease, Symptomatic arrhythmia Hypoxia at rest (Oxygen saturation (SPO2)< 88%) Pulmonary artery hypertension (Pulmonary Artery Pressure(PAP) > 30mmHg) Fever or Acute systemic disease Uncontrolled Diabetes Mellitus(DM) Severe Orthopedic or Neurological problems that prevent exercise Other metabolic conditions such as: Acute thyroiditis, Hyperkalemia, Hypokalemia and Hypovolemia (Until adequate treatment) Severe Psychological disorders Poor compliance Problem transporting the patient to the Rehabilitation Center Absence of the patient from rehabilitation sessions (More than 2 sessions)
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **27**
Actual sample size reached: **27**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Vice Chancellor for Research and Technology of Mazandaran University of Med
Street address
Moallem Square, Vice Chancellor for Research and Technology, Mazandaran University of Medical Sciences
City
Sari
Province
Mazandaran
Postal code
4815733971
Approval date
2020-09-19, 1399/06/29
Ethics committee reference number
IR.MAZUMS.REC.1400.148

Health conditions studied

1

Description of health condition studied
Novel Coronavirus(COVID-19)
ICD-10 code
U07.1
ICD-10 code description
Clinically-epidemiologically diagnosed COVID-19

2

Description of health condition studied
Intensive Care Unit Acquired Weakness
ICD-10 code
G72.81
ICD-10 code description
Critical illness myopathy

Primary outcomes

1

Description
Quality of life
Timepoint
Before the intervention and after the intervention (after 16th session)
Method of measurement
World Health Organization Questionnaire

2

Description
Peripheral muscle force
Timepoint
Before the intervention and after the intervention (after 16th session)
Method of measurement
Medical Research Council grading system

Secondary outcomes

1

Description
Inspiratory muscle strength
Timepoint
Before the intervention and after the intervention (after 16th session)
Method of measurement
Assessment of Maximal inspiratory pressure(MIP) with Power Breath KH5 device

2

Description
Ability to perform activity of daily living(ADL)
Timepoint
Before the intervention and after the intervention (after 16th session)
Method of measurement
Katz Questionnaire

3

Description
Assess the level of anxiety and depression
Timepoint
Before the intervention and after the intervention (after 16th session)
Method of measurement
Hospital Anxiety and Depression Scale(HADS) Questionnaire

4

Description
Evaluation of muscle mass changes
Timepoint
Before the intervention and after the intervention (after 16th session)
Method of measurement
Bioelectrical impedance analysis device(BIA)

5

Description
The degree of dyspnea
Timepoint
Before the intervention and after the intervention (after 16th session)
Method of measurement
Modified Medical Research Council(MMRC) Dyspnea scale

6

Description
Evaluation of changes in Exercise capacity
Timepoint
Before the intervention and after the intervention (after 16th session)
Method of measurement
6 Minutes walk test

Intervention groups

1

Description
Intervention group: Patients return to the rehabilitation center three weeks after discharge from the hospital, and the rehabilitation program will be designed twice a week for two months (16 sessions in total) and the duration of each session will be approximately 40 minutes for each patient. Exercises for each session include: warm up and cool down, strength exercises for the upper and lower limbs, and Inspiratory muscle training (IMT) with the KH5 digital Power Breath (start with a resistance of 30% of maximal inspiratory pressure) . Aerobic exercise with a stationary bike and treadmill also starts according to the patient's ability and gradually increases its duration and intensity. Gradually increase the intensity of the exercises during the sessions (in Aerobic , strength and breathing exercises) in proportion to the individual's progress. All sessions will be performed under supervision. Vital signs and oxygen saturation(SPO2) will be checked at the beginning of each session. After the rehabilitation sessions, the initial examinations (includes: peripheral and inspiratory muscle strength, 6-minute walk test, dyspnea scale, anxiety and depression scale, quality of life, body mass analysis)will be repeated.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Atefeh Najafi
Street address

Sari, Amir Mazandarani St., Imam Khomeini Hospital

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2

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Hanie Adib

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Majid Saeeidi

Street address
Moallem Square, Department of Research and Technology

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Grant name
1290004

Grant code / Reference number
۱۶۰۲۰۰۱۰۰۰

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Hanie Adib

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Sport Medicine

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Position
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Latest degree
Specialist

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Person responsible for updating data

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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 recorded data will be reachable for clinical and academic researchers for one year after the article publications as non-identifiable files
When the data will become available and for how long
Accessibility to the data will be possible 6 months after the article publication for the applicants, for one year.
To whom data/document is available
Academic researchers and clinicians
Under which criteria data/document could be used
It is allowed only with the permission of the head researcher, and with the condition of participating in the research.
From where data/document is obtainable
Refer to the Email Address of the researchers: hanieadib@gmail.com atefehnajafi66102@gmail.com
What processes are involved for a request to access data/document
The request must be emailed to corresponding author. ID card and reason for the request must be sent . Once confirmed , the data will be emailed within a week.
Comments