

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 11 3326 4163

Email address

hanieadib@gmail.com

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

City

Sari

Province

Mazandaran

Postal code

۳۳۱۳۱ ۴۸۱۶۶

Phone

+98 11 3304 4000

Email

hanieadib@gmail.com

Web page address

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

2

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Hanie Adib

Street address

Yousef Reza Ave, Ghaemshahr, Mazandaran

City

Qaemshahr

Province

Mazandaran

Postal code

۴۵۶۵۶۸۶۱۳۳

Phone

+98 11 4221 8018

Email

razi-ghh@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Moallem Square, Department of Research and Technology

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3325 7230

Email

pajoheshi@mazums.ac.ir

Grant name

1290004

Grant code / Reference number

۱۶۰۲۰۰۱۰۰۰

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

Yes

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

Street address

No 6, 3th Ave, Razi St, Mostafavian Clinic , Sports Medicine Clinic

City

Sari

Province

Mazandaran

Postal code

4816868890

Phone

+98 11 3336 6552

Email

hanieadib@gmail.com

Person responsible for scientific 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

Street address

No 6, 3th Ave, Razi St, Mostafavian Clinic , Sports Medicine Clinic

City

Sari

Province

Mazandaran

Postal code
4816868890
Phone
+98 11 3336 6552
Email
hanieadib@gmail.com

Person responsible for updating data

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
Street address
No 6, 3th Ave, Razi St, Mostafavian Clinic , Sports
Medicine Clinic
City
Sari
Province
Mazandaran
Postal code
4816868890
Phone
+98 11 3336 6552
Email
hanieadib@gmail.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

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