# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Nov 2026

## Investigating the effect of aerobic exercise on immune and inflammatory indicators in patients improved from COVID-19

### Protocol summary

**Study aim**
The effect of aerobic activity on immune and inflammatory system indicators in recovered patients of COVID-19

**Design**
This research is a clinical trial, semi-experimental field type. Among the male patients recovered from COVID--19 , 24 people are voluntarily selected under the supervision of a doctor specializing in infectious diseases and based on the inclusion criteria. Volunteers are placed in two groups of aerobic exercise and control based on a simple random method and in the form of a lottery.

**Settings and conduct**
Place of study: Khorramshahr University of Marine Sciences and Techniques, study population: patients with COVID-19, blinding is not done in this study.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Male patients recovered from COVID-19; Maximum oxygen consumption at least 25; Ability to participate in the training program; No other diseases. Non-inclusion criteria: having sports activity during the last 6 months; taking medication

**Intervention groups**
Intervention group: Aerobic exercise group that implements the aerobic exercise protocol including 3 sessions per week for eight weeks with an intensity of 50 to 70% of the reserve heart rate. Control group: who do not perform any regular physical activity during the training period.

**Main outcome variables**
Interleukin 6 (IL-6); Interleukin 10 (IL-10); C-Reactive Protein (CRP); Leukocytes; Lymphocytes; Neutrophils; Monocytes

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20221012056156N1**
Registration date: **2023-07-02, 1402/04/11**
Registration timing: **retrospective**

Last update: **2023-07-02, 1402/04/11**
Update count: **0**

**Registration date**
2023-07-02, 1402/04/11

**Registrant information**

**Name**
Davar Rezaeimanesh

**Name of organization / entity**
Khorramshahr university of Marine Science and Technology

**Country**
Iran (Islamic Republic of)

**Phone**
+98 61 5353 3819

**Email address**
d.rezaimanesh@kmsu.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-02-04, 1401/11/15

**Expected recruitment end date**
2023-03-11, 1401/12/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Investigating the effect of aerobic exercise on immune and inflammatory indicators in patients improved from

COVID-19

**Public title**
The effect of aerobic activity on recovered patients from COVID-19
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Male patients who recovered from COVID-19 VO2 max above 25 mL/Kg.min-1 Ability to participate in the training program
**Exclusion criteria:**
participation in sports within the past year Taking medicines Smoking and alcohol drinking Suffering from other diseases
**Age**
From **18 years** old to **30 years** old
**Gender**
Male

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **24**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
First, calls are made in Abadan and Khorramshahr cities. Then, among the volunteers who declare their readiness, 24 are selected based on the criteria for entering the research. Subjects are placed in two groups by simple random method. In the simple random method, lottery is used. In this way, each person is assigned a number. Then the folded sheets containing the number of each candidate are placed in a container. Based on the lottery, the above numbers will be placed in two aerobic training group (12 people) and the control group (12 people), respectively.
**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 Abadan University of Medical Sciences
**Street address**
At the beginning of Simeteri-e-Zulfikari
**City**
Abadan
**Province**
Khouzestan
**Postal code**
631981115426
**Approval date**
2022-09-18, 1401/06/27
**Ethics committee reference number**
IR.ABADANUMS.REC.1401.067

## Health conditions studied

### 1

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

## Primary outcomes

### 1

**Description**
IL-6 plasma levels
**Timepoint**
One day before the training protocol and 48 hours after the last training session
**Method of measurement**
special kit

### 2

**Description**
IL-10 plasma levels
**Timepoint**
One day before the training protocol and 48 hours after the last training session
**Method of measurement**
special kit

### 3

**Description**
C-Reactive Protein – CRP
**Timepoint**
One day before the training protocol and 48 hours after the last training session
**Method of measurement**
special kit

### 4

**Description**
Leukocytes
**Timepoint**
One day before the training protocol and 48 hours after the last training session

**Method of measurement**
special kit

**5**

**Description**
Lymphocytes
**Timepoint**
One day before the training protocol and 48 hours after the last training session
**Method of measurement**
special kit

**6**

**Description**
Neutrophils
**Timepoint**
One day before the training protocol and 48 hours after the last training session
**Method of measurement**
special kit

**7**

**Description**
Monocytes
**Timepoint**
One day before the training protocol and 48 hours after the last training session
**Method of measurement**
special kit

## Secondary outcomes

**1**

**Description**
Maximum oxygen consumption
**Timepoint**
Before and after the intervention
**Method of measurement**
Rockport walking test

## Intervention groups

**1**

**Description**
Intervention group: The intensity of training in the first four weeks is 50 to 60% of the maximum reserve heart rate, and from the fifth to the eighth week, 60 to 70% of the reserve heart rate is considered. The training time started from 15 minutes in the first week and 5 minutes are added to the training time every week until the fourth week. Due to the increase in training intensity, 20 minutes will be added to the training time in the fifth week and 5 minutes will be added to the training time every week until the end of the training period.
**Category**
Behavior

**2**

**Description**
Control group: they don't receive any exercise intervention.
**Category**
Behavior

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Abadan Taleghani Hospital
**Full name of responsible person**
Davar Rezaeimanesh
**Street address**
Ayatollah Taleghani Hospital; Station 12; In front of Azad University
**City**
Abadan
**Province**
Khouzestan
**Postal code**
6316953111
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davarrezaee@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
University of Marine Sciences and Technologies
**Full name of responsible person**
Davar Rezaeimanesh
**Street address**
Koi-e-Asatid Street
**City**
Khorramshahr
**Province**
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**Postal code**
6318911154
**Phone**
+98 61 5353 1938
**Email**
davarrezaee@yahoo.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
University of Marine Sciences and Technologies
**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**

Khorramshahr Marine Science and Technology University

**Full name of responsible person**

Davar Rezaeimanesh

**Position**

Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology of exercise

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## Person responsible for scientific inquiries

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**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

University of Marine Sciences and Technologies

**Full name of responsible person**

Davar Rezaeimanesh

**Position**

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**Latest degree**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available