

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Investigating the effectiveness of selenium on recovery of hospitalized patients with COVID-19

Protocol summary

Study aim

In this study, we will examine the effect of Selenium administration on the physical burden associated with ARDS, mortality, and the need for hospitalization in patients diagnosed with COVID-19 at early stages

Design

A double-blinded randomized controlled trial

Settings and conduct

100 patients who meet the eligibility criteria will be selected to participate in this study. Participants will be randomized into two groups using a simple permuted block randomization technique. Participants in the control group will receive the hospital's standard protocol for the treatment of COVID-19. The intervention group will receive 200 micrograms of selenium daily in addition to the standard treatment protocol. Routine laboratory tests, mortality rates, and the need for hospitalization will be measured.

Participants/Inclusion and exclusion criteria

The patient will be included in this study if they: -Being diagnosed with COVID-19 using the RT-PCR test - having a breathing rate > 30 per minute - Arterial blood oxygen saturation levels < 90% - PaO₂/FiO₂ ratio < 300 mmHg - Elevated serum levels of interleukin-6 - Patients above 18 years of age

Intervention groups

Control group: Participants in the control group will receive the standard protocol treatment. standard protocol treatment consists of 400 mg Hydroxychloroquine twice daily on day one, followed by 200 mg twice per day. Intervention group: In addition to the standard protocol treatment, patients in the intervention group will receive 200 micrograms selenium daily for at least 2 weeks. Routine blood tests, the need for hospitalization, and the mortality rate will be measured as the study outcomes.

Main outcome variables

-Routine laboratory tests (changes in ferritin, platelet, WBC, CRP) -Mortality rates -the need for hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190418043307N1**

Registration date: **2020-05-17, 1399/02/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-17, 1399/02/28**

Update count: **0**

Registration date

2020-05-17, 1399/02/28

Registrant information

Name

Elham Shafiei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3223 5700

Email address

shafiei-e@medilam.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-26, 1399/02/07

Expected recruitment end date

2020-06-27, 1399/04/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of selenium on recovery of hospitalized patients with COVID-19

Public title

Effect of selenium on covid-19 disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of COVID-19 by RT-PCR test
Respiratory rate above 30 bar per minute
Percentage of peripheral blood oxygen saturation less than 90%
Relative oxygen depletion ratio to arterial oxygen saturation less than 300 mm Hg
Interloquin six blood levels higher
Abnormally age over 18 years

Exclusion criteria:

chronic kidney disease
acute kidney failure
Pregnancy or lactation
History of drug allergy
Pneumonia caused by H influenza, viral infections, bacterial infections, fungi; and other noninfectious types of pneumonia
Chronic liver disease
history of latent or active tuberculosis
patients with acquired immunodeficiency syndrome

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The first phase involves the screening process of potential patients by the researcher to identify the eligibility to participate based on the study inclusion and exclusion criteria. The research assistant will contact eligible participants for enrollment. Those patients who agree to take part in the study will be provided with the information sheet and written consent form before baseline assessment at enrolment. 100 Patients with Covid-19 will be randomized sequentially at the time they provided a baseline assessment. Randomization will be generated by permuted block randomization with allocation concealment. Participants will be divided into intervention or control groups. The control group will receive only the standard protocol treatment, but the intervention group will receive the selenium for 2 weeks in addition to the standard protocol treatment.

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 Ilam University of Medical Sciences

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6931854919

Approval date

2020-04-14, 1399/01/26

Ethics committee reference number

IR.MEDILAM.REC.1399.010

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**

Ferritin changes

Timepoint

Daily

Method of measurement

Laboratory

2**Description**

platelet

Timepoint

Daily

Method of measurement

Laboratory

3**Description**

CRP

Timepoint

Daily

Method of measurement

Laboratory

4**Description**

WBC changes

Timepoint

Daily

Method of measurement

Laboratory

Secondary outcomes**1****Description**

Reduced mortality

Timepoint

Day 1 to 14

Method of measurement

Record the time of death

Intervention groups**1****Description**

Intervention group: In addition to the standard protocol treatment, patients in the intervention group will receive 200 micrograms selenium daily for at least 2 weeks. Routine blood tests, the need for hospitalization, and the mortality rate will be measured as the study outcomes.

Category

Treatment - Drugs

2**Description**

Control group: Participants in the control group will receive the standard protocol treatment. standard protocol treatment consists of 400 mg Hydroxychloroquine twice daily on day one, followed by 200 mg twice per day.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Mostafa Khomeini Hospital

Full name of responsible person

Ali Nazari

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy Dean of Research and Technology, Ilam university of medical science

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

Deputy Dean of Research and Technology, Ilam university of medical science

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**

Ilam University of Medical Sciences

Full name of responsible person

Ali Nazari

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious Disease Specialist

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Person responsible for updating data

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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