Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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+98 84 3223 5700

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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
Street address
modares Ave
City
Ilam
Province
Ilam
Postal code
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
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Full name of responsible person
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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
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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