

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Sep 2026

The effect of selenium supplementation on inflammatory markers and blood cells in patients with Covid 19 double-blind randomized clinical trial

Protocol summary

Study aim

The effect of selenium supplementation on inflammatory markers and blood cells in patients with Covid 19 double-blind randomized clinical trial

Design

This study is a randomized double-blind controlled clinical trial with parallel groups. Random assignment of individuals to the intervention or control group will be done using SPSS software.

Settings and conduct

The study will be performed at Imam Khomeini Hospital in Tehran. The evaluation of variables is done at the beginning and end of the study by sampling the patient's blood. The intervention group received selenium supplementation for two weeks and the control group received the same number of placebo.

Participants/Inclusion and exclusion criteria

We will invite 40 patients with COVID-19 based on inclusion and non-inclusion criteria. Inclusion criteria: 1. Being 20 to 60 years old 2. Diagnosis of COVID-19 based on PCR test 3. Willingness to participate in study 4 Not breastfeeding and not pregnant 5. No advanced respiratory distress syndrome leading to intubation. Exclusion criteria during the study Use of antioxidant supplements during the study.

Intervention groups

Intervention group: includes 20 patients with COVID-19 who, in addition to their usual treatments, will take 1 capsule of 200 micrograms of selenium daily for 2 weeks (14 days) after meals. Control group: includes 20 patients with COVID-19 who, in addition to their usual treatments, will take 1 placebo tablet (maltodextrin) daily for 2 weeks after meals. Placebo capsules are very similar in appearance, color, smell and shape to selenium capsules.

Main outcome variables

1. Serum level of C-reactive protein 2. Serum level of interleukin-6 3. Total number of leukocytes 4. Total number of lymphocytes 5. Total number of neutrophils

General information

Reason for update

Due to the fact that the diagnostic parameters of Covid_19 have changed over the past year, and now the relevant experts use laboratory indicators such as ferritin and lactate dehydrogenase to determine the degree of inflammation caused by the disease, as well as the healing process and the status of Covid_19 patients. Therefore, according to the experts in this field as well as the professors of the infectious diseases and lungs, we decided to add these two laboratory variables to our study. Therefore, in vitro parameters of ferritin and lactate dehydrogenase were added to the initial outcome variables.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210427051100N1**
Registration date: **2021-06-19, 1400/03/29**
Registration timing: **prospective**

Last update: **2021-12-10, 1400/09/19**

Update count: **1**

Registration date

2021-06-19, 1400/03/29

Registrant information

Name

amirhossein hemati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5534 5434

Email address

ah-hemati@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-30, 1400/04/09

Expected recruitment end date

2021-07-31, 1400/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of selenium supplementation on inflammatory markers and blood cells in patients with Covid 19 double-blind randomized clinical trial

Public title

selenium in covid_19

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Detection of COVID-19 based on PCR tests Being 20 to 60 years old Willingness to participate in the study

Exclusion criteria:

Breastfeeding and pregnancy Advanced respiratory distress syndrome leading to intubation

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Due to the fact that the sample size of these studies is 40 people, to maintain the balance between the two groups, the block randomization method will be used so that 10 four-person blocks including 2 people in the intervention group and 2 others in the placebo group will be formed and distinguished. The placement of individuals in each block will be using a table of random numbers so that in the table of random numbers from top to bottom even numbers will be assigned to the intervention group and odd numbers to the placebo group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The subjects will be assigned to two groups receiving selenium supplementation and placebo group. The subjects in the intervention group, in addition to their usual treatments, will take 1 capsule of 200 micrograms daily for 2 weeks, and the placebo group will have 1

capsule of placebo daily, which is completely similar in appearance, color, smell and shape to selenium capsules. . The placebo capsule will contain maltodextrin. Supplements and placebos will be provided to patients by a third party who is not directly involved in the research process. Therefore, all patients and researchers will be unaware of the existing grouping. To assess patient admission, a checklist will be prepared and provided to the patient and they will be asked to record their daily intake.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Medical School Research - Tehran University of Medical Sciences

Street address

Central Headquarters of Tehran University of Medical Sciences, Corner of Ghods, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

3439123900

Approval date

2021-04-17, 1400/01/28

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.046

Health conditions studied**1****Description of health condition studied**

Covid-19

ICD-10 code

U07.1 COVI

ICD-10 code description

U07.1 COVICOID-19 , virus identified

Primary outcomes**1****Description**

Serum levels of reactive protein-C

Timepoint

The first day and the last day of the intervention

Method of measurement

Blood test

2

Description

Serum levels of interleukin-6

Timepoint

The first day and the last day of the intervention

Method of measurement

Using blood sampling, the amount of serum IL6 in pc / dl by the kit

3

Description

Blood leukocyte count

Timepoint

The first day and the last day of the intervention

Method of measurement

blood test

4

Description

Complete number of lymphocytes

Timepoint

The first day and the last day of the intervention

Method of measurement

blood test

5

Description

Complete number of neutrophils

Timepoint

The first day and the last day of the intervention

Method of measurement

blood test

6

Description

Lactate Dehydrogenase

Timepoint

The first day and the last day of the intervention

Method of measurement

blood test

7

Description

ferritin

Timepoint

The first day and the last day of the intervention

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: includes 20 patients with COVID-19 who, in addition to their usual treatments, will take 1 capsule of 200 micrograms of selenium daily for 2 weeks (14 days) after meals.

Category

Treatment - Drugs

2

Description

Intervention group: Control group: includes 20 patients with COVID-19 who, in addition to their usual treatments, will take 1 placebo tablet (maltodextrin) daily for 2 weeks (14 days) after meals. Placebo capsules are very similar in appearance, color, smell and shape to selenium capsules.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr. Azar Hadadi

Street address

Iran - Tehran - Imam Khomeini St. - Has not reached Hassan Abad Square-Sina Hospital Medical, Educational and Medical Center

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Tehran

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1136746911

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hosp_sina@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mr. Dr. Sahraian

Street address

Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Vice Chancellor for Research and Technology

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Web page address
 http://en.tums.ac.ir/en
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Tehran 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

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Full name of responsible person
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 3439123900
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Email
 amirhemati2000@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 information can be shared two months after the results are published

When the data will become available and for how long

Two months after the publication of the results

To whom data/document is available

Physicians, nurses, and infectious disease specialists

Under which criteria data/document could be used

To evaluate other complementary therapies and compare its effect with existing treatment related to COVID-19 disease

From where data/document is obtainable

Send an email to mortezakhamoushi@gmail.com

What processes are involved for a request to access data/document

Two months after the results are published, send a written request to mortezakhamoushi@gmail.com. In this case, and finally within one month after receiving the email, the request will be answered.

Comments