Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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 COVICOVID-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
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 4561 7676
Email
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
City
Tehran
Province

Tehran
Postal code
14155-6117
Phone
+98 21 8163 3685
Email
vcr@tums.ac.ir
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

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Amirhossein hemati
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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Student
Latest degree
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Other areas of specialty/work
Nutrition
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Faculty of Nutrition and Dietetics, University of Medical Sciences and Health Services, Tehran, Keshavarz Blvd., Naderi St., Hojjatdoost Alley, No. 44
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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