Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The effect of zinc supplementation on inflammatory responses and total blood cells counts of patients who infected with COVID-19

Protocol summary

Study aim
Determining the effect of zinc supplementation on inflammatory activity and blood cell status in patients with COVID-19

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

Settings and conduct
The study will be performed at Shohada Tajrish Hospital in Tehran. The evaluation of variables will be done at the beginning and end of the study by sampling the patient's blood. The intervention group will receive zinc gluconate supplementation for two weeks and the control group will receive the same number of placebo.

Participants/Inclusion and exclusion criteria
We will invite 44 patients with COVID-19 to enter the study based on inclusion and exclusion criteria. Inclusion criteria: 1. Being 20 to 60 years old 2. Detection of COVID-19 based on PCR test 3. Willingness to participate in the study 4. Do not take antibiotics and vitamin D 5. Not breastfeeding or pregnant 6. No advanced respiratory distress syndrome leading to intubation 7. No history of alcohol and tobacco use Exclusion criteria: 1. Taking antioxidant supplements while studying 2. Alcohol and tobacco consumption during the study

Intervention groups
Intervention group: Includes 22 patients with COVID-19 who, in addition to their usual treatments, will take 3*30 mg zinc capsules daily for 2 weeks after meals. Control group: Includes 22 patients with COVID-19 who, in addition to their usual treatments, will take 3 placebo capsules (maltodextrin) daily for 2 weeks after meals. Placebo capsules are exactly the same in appearance, color, smell and shape as zinc capsules.

Main outcome variables
1. Serum C-Reactive Protein level 2. Serum Interleukin-6 level 3. leukocyte count 4. Total Lymphocyte Count 5. Absolute neutrophil count

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210204050238N1**
Registration date: **2021-03-02, 1399/12/12**
Registration timing: **prospective**

Last update: **2021-03-02, 1399/12/12**
Update count: **0**

Registration date
2021-03-02, 1399/12/12

Registrant information

Name
Morteza Khamoushi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8895 5975

Email address
mortezakhamoushi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-21, 1400/01/01

Expected recruitment end date
2021-07-22, 1400/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of zinc supplementation on inflammatory responses and total blood cells counts of patients who infected with COVID-19

Public title
The effect of zinc supplementation on COVID-19

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Being 20 to 60 years old Detection of COVID-19 based on PCR test and ward admission Willingness to participate in the study Intravenous daily intake of 8 mg dexamethasone

Exclusion criteria:
Taking antibiotics and vitamin D. Advanced Respiratory Distress Syndrome leading to intubation or hospitalization in the intensive care unit History of alcohol and tobacco use

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Each person is assigned a code and this code is entered into Excel software, randomization will be done using rand function of Excel software.

Blinding (investigator's opinion)
Double blinded

Blinding description
Physicians and ward nurses are blind about the study group. Patient is blind about the study group. investigator is blind about the study group. data analyzer is blind about the study group. Assignment of patients in treatment and placebo groups is performed by a nurse out of above mentioned groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice-Chancellor in Research Affairs- Tehran University of Medical Sciences

Street address
central headquarters of Tehran University of Medical Sciences, Keshavarz Boulevard, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
3439123900

Approval date
2020-12-05, 1399/09/15

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.849

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1 COVI

ICD-10 code description
COVID-19 , virus identified

Primary outcomes

1

Description
Serum C-Reactive Protein level

Timepoint
The first day and the last day of the intervention

Method of measurement
blood analysis

2

Description
Serum Interleukin-6 level

Timepoint
The first day and the last day of the intervention

Method of measurement
Using blood, serum IL-6 value in Picograms per deciliter by Kit

3

Description
blood leukocyte count

Timepoint
The first day and the last day of the intervention

Method of measurement
blood analysis

4

Description
Total Lymphocyte Count
Timepoint
The first day and the last day of the intervention
Method of measurement
blood analysis

5

Description
Absolute neutrophil count
Timepoint
The first day and the last day of the intervention
Method of measurement
blood analysis

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Includes 22 patients with COVID-19 who, in addition to their usual treatments, will take 3*30 mg zinc capsules daily for 2 weeks (14 days) after meals.
Category
Treatment - Drugs

2

Description
Control group: Includes 22 patients with COVID-19 who, in addition to their usual treatments, will take 3 placebo capsules (maltodextrin) daily for 2 weeks (14 days) after meals. Placebo capsules are exactly the same in appearance, color, smell and shape as zinc capsules.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Tajrish Educational Hospital
Full name of responsible person
Dr. Reza Jalili Khoshnood
Street address
Shohadaye Tajrish Educational Hospital Tajrish Sq., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 25719
Email
Pr_shohada@sbmu.ac.ir
Web page address
http://shmc.sbmu.ac.ir/index.jsp?fkeyid=&siteid=90&pageid=47435

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
آقای دکتر صحراییان
Street address
Vice Chancellor for Research and Technology, Central University Organization, sixth floor, corner of Quds Street, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
14155-6117
Phone
+98 21 8163 3685
Fax
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
Seyed Morteza Seyed khamoushi
Position
Student
Latest degree

Bachelor

Other areas of specialty/work
Nutrition

Street address
School of Nutritional Sciences & Dietetics, Tehran University of Medical Sciences, No: 44 Hojjat-dost Alley, Naderi St., Keshavarz Blvd, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
3439123900

Phone
+98 21 8895 5975

Fax
+98 21 8898 4861

Email
mortezakhamoushi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Hossein Imani

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
School of Nutritional Sciences & Dietetics, Tehran University of Medical Sciences, No: 44 Hojjat-dost Alley, Naderi St., Keshavarz Blvd, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
3439123900

Phone
+98 21 8895 5975

Fax
+98 21 8898 4861

Email
h-imani@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Seyed Morteza Seyed khamoushi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

Street address
School of Nutritional Sciences & Dietetics, Tehran University of Medical Sciences, No: 44 Hojjat-dost Alley, Naderi St., Keshavarz Blvd, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
3439123900

Phone
+98 21 8895 5975

Fax
+98 21 8898 4861

Email
mortezakhamoushi@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 results are published.

To whom data/document is available
Doctors, nurses, and infectious disease specialists

Under which criteria data/document could be used
To evaluate other complementary therapies and compare their effects with existing COVID-19 therapy

From where data/document is obtainable
Send email to mortezakhamoushi@gmail.com

What processes are involved for a request to access data/document
Two months publishing results, send a clear written request by sending an email to mortezakhamoushi@gmail.com. In this case, and finally within one month after receiving the email, the request will be answered.

Comments