

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

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Phone

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Email

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Web page address

<http://shmc.sbm.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 صحراييان

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Dr. Hossein Imani

Position

Associate professor

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Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

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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