Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Effect of zinc supplementation in diagnosed cases of 2019 Novel Coronavirus (SARS-CoV-2); a randomized clinical trial

Protocol summary

Study aim
Determining the effect of supplementation on improving the clinical and experimental status of patients with the disease Evaluation of the effect of adjuvant supplementation on the length of hospital stay in patients with the disease Evaluation of the effect of supplementation or on the severity of symptoms in patients with the disease Evaluating the effect of McNell help on mortality in patients with the disease Evaluation of the relationship between plasma levels and the severity of clinical and experimental findings in patients with some form

Design
A randomized, double-blind, randomized controlled clinical trial on 140 patients. A table of random numbers is used for randomization

Settings and conduct
The intervention will be performed in two groups as follows: Group one: Consumption of 50 mg zinc supplement daily Group two: placebo Blood samples are taken before and after the intervention This intervention will be carried out in Mashhad-Iran Blinding will be done for individuals and researchers

Participants/Inclusion and exclusion criteria
Exclusion criteria: Participate in another randomized trial study Inclusion criteria: Age 18 to 65 years Diagnosis of Qovid 19 infection based on the approval of a specialist

Intervention groups
Intervention group: Daily consumption of 50 mg zinc supplement Control group: receiving place

Main outcome variables
death; Inflammatory factors; Duration of hospitalization; Severity of symptoms; Clinical and laboratory status

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211112053046N1**
Registration date: **2021-11-25, 1400/09/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-25, 1400/09/04**
Update count: **0**

Registration date
2021-11-25, 1400/09/04

Registrant information

Name
Zahra Lotfi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3842 8041

Email address
lotfiz@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-17, 1400/08/26

Expected recruitment end date
2022-08-17, 1401/05/26

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of zinc supplementation in diagnosed cases of 2019 Novel Coronavirus (SARS-CoV-2); a randomized clinical trial

Public title

Effect of zinc supplementationin diagnosed cases of 2019 novel coronavirus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of COVID-19 infection is subject to the approval of a specialist Age 18 to 65 years

Exclusion criteria:

addict Allergy to zinc Pregnancy and lactation Occurrence of special medical conditions History of AIDS and chronic lung disease History of corticosteroids and chemotherapy drugs in the past month Use of drugs that affect metabolism Use multivitamin supplements that are more than 10 mg per day

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **140**

More than 1 sample in each individual

Number of samples in each individual: **2**

Surface crp surface relative to copper to zinc surface relative to neutrophil to lymphocyte LDH level

Randomization (investigator's opinion)

Randomized

Randomization description

In order to create a balance in the number of samples assigned to each of the groups studied, individuals are randomly divided into two groups by blocking method: Accordingly, because we have two groups, the allocation is done in the form of AB, BA and after reaching To the desired volume, it is randomly determined whether group A or B is the intervention group or placebo.Each patient is randomly assigned to one of the two intervention or control groups. Randomization is done in such a way that the type of treatment (intervention group or control group) is placed in closed envelopes and then one envelope is randomly assigned to each patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blind study: In this type of study, both participants and researchers are not initially aware that the individual is in the control or intervention group, and neither participants nor researchers are aware of the allocation of medication or placebo to patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Azadi Square, Campus of Mashhad University of Medical Sciences, School of Medicine

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948546

Approval date

2021-07-03, 1400/04/12

Ethics committee reference number

IR.MUMS.REC.1400.111

Health conditions studied

1

Description of health condition studied

Covid_19

ICD-10 code

U07.1

ICD-10 code description

Use this code when COVID-19 has been confirmed by laboratory testing irrespective of severity of clinical signs or symptoms. Use additional code, if desired, to identify pneumonia or other manifestations

Primary outcomes

1

Description

Level CRP

Timepoint

Measurement of reaction level _ thirty before the intervention and 14 days after starting zinc supplementation

Method of measurement

Enzyme-dependent immunosorbent assay kit

Secondary outcomes

1

Description
Level of neutrophil to lymphocyte ratio
Timepoint
Measurement of neutrophil to lymphocyte ratio level before intervention and 14 days after zinc supplementation
Method of measurement
Microscopic counting

Intervention groups

1

Description
Intervention group:50 mg zinc tablets as a single dose made by Alhawi company for 14 days daily with lunch
Category
Treatment - Drugs

2

Description
Control group: Placebo tablets, 14 days, with lunch, slaughtered in the Department of Pharmacology, Mashhad University of Medical Sciences
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr. Seyedeh Zahra Lotfi
Street address
Azadi Square, Campus of Mashhad University of Medical Sciences, School of Medicine
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Lotfiz@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Azadi Square, Campus of Mashhad University of Medical Sciences, School of Medicine
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Seyedeh Zahra Lotfi
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific

inquiries

Contact

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Full name of responsible person
Dr. Seyedeh Zahra Lotfi

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Omolbanin hajhoseini

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Patients' identities will be kept confidential and will not be published anywhere

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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
The study protocol will be published and made available to researchers after the end of the study.

When the data will become available and for how long
Start of access protocol period to articles from 1401

To whom data/document is available
Academic and scientific researchers can apply to receive

Under which criteria data/document could be used
Scientific articles of this project can be used by researchers

From where data/document is obtainable
To receive articles, please contact the following email: lotfiz@mums.ac.ir

What processes are involved for a request to access data/document
If articles and protocols are published, they can receive them via email

Comments