

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Effect of Selenium on improvement of clinical manifestations and reducing hospitalization in patients with COVID 19

Protocol summary

Study aim

Effect of Selenium on improvement of clinical manifestations and reducing hospitalization in patients with COVID 19

Design

Clinical trial with control group and parallel groups, double blind, with using a permuted balanced block randomization method with the size of blocks 4 and 6, phase 3 on 160 patients, Random sequence will be generated by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>).

Settings and conduct

The aim of this study is evaluation of Selenium effect on reducing clinical manifestation of COVID19. Locality of the study is in Amiralmomenin and Valie-asr hospital of Arak city. In Selenium group, 1 mg of selenium intravenously will be injected for 14 days added to routine treatment protocol and in control group distilled water that is similar to Selenium will be given to the patients (in addition to routine treatment) for 14 days, too.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with moderate COVID 19 infection
Patients with severe COVID 19 infection
Patients who have informed consent
Non-inclusion criteria: Renal failure (Glomerular filtration rate 70 or under)

Intervention groups

In Selenium group, 1 mg of selenium intravenously will be injected for 14 days added to routine treatment protocol and in control group distilled water that is similar to Selenium will be given to the patients (in addition to routine treatment).

Main outcome variables

Need of mechanical ventilation and duration of using, length of hospitalization, length of ICU stay, duration of fever, level of SpO2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201028049175N9**

Registration date: **2021-09-06, 1400/06/15**

Registration timing: **prospective**

Last update: **2021-09-06, 1400/06/15**

Update count: **0**

Registration date

2021-09-06, 1400/06/15

Registrant information

Name

Shamim Valibak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3502

Email address

sh.valibak@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-22, 1400/06/31

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Selenium on improvement of clinical manifestations and reducing hospitalization in patients with COVID 19

Public title

Effect of Selenium on improvement of clinical manifestations and reducing hospitalization in patients with COVID 19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with moderate COVID 19 infection Patients with severe COVID 19 infection Patients who have informed consent

Exclusion criteria:

Renal failure (Glomerular filtration rate 70 or under)

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Sequences web randomization (www.graphpad.com) dual group for creation of simple randomization and for concealment, closed envelope method with random sequence (SNOSE) will be used. Random sequences will be written on the cards and then sequentially put in the envelopes. In order to preserve random sequences, the outer surface of the envelopes are numbered, respectively. Finally, the lid of the envelopes will be paste and place inside the boxes, respectively. At the time of participants registration, one of the envelopes will be open and the allocation group will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

All patients have informed consent to entrance to study, but they do not know about the kind of drugs have been received . The required drugs will be prescribed by the infectionist and anesthesiologist, but the person who will gather the data of patients outcomes will be unaware about the patients group and the kind of received drugs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Assistance of research and technology, Payambare azam institution, Arak University of Medical Sciences, Basij square

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2021-08-08, 1400/05/17

Ethics committee reference number

IR.ARAKMU.REC.1400.123

Health conditions studied

1

Description of health condition studied

Coronavirus disease 2019 (COVID 19)

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

2

Description of health condition studied

Selenium

ICD-10 code

E59

ICD-10 code description

Dietary selenium deficiency

Primary outcomes

1

Description

Length of hospitalization

Timepoint

After discharge

Method of measurement

Days

2

Description

Length of ICU stay

Timepoint

After discharge

Method of measurement

Days

3

Description

Duration of using mechanical ventilation

Timepoint

After discharge

Method of measurement

Days

4

Description

Duration of fever

Timepoint

After discharge

Method of measurement

Days

5

Description

Level of atrial oxygen saturation (SpO2)

Timepoint

Daily from first day to 14th day

Method of measurement

pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1 mg of selenium intravenously will be injected for 14 days added to routine treatment protocol.

Category

Treatment - Drugs

2

Description

Control group: Distilled water that is similar to Selenium will be given to the patients for 14 days (in addition to routine treatment).

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Amiralmomenin hospital

Full name of responsible person

Hossein Sarmadian

Street address

Amiralmomenin hospital street, Basij square

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2

Recruitment center**Name of recruitment center**

Valie-asr hospital

Full name of responsible person

Behnam Mahmoodieh

Street address

Valie-asr square

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3814957558

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Hossein Sarmadian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Parastar square, Rah-ahan square, Shiroudi street

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Behnam Mahmoodieh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Shamim Valibak

Position

General physician non-faculty

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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