

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2020

The effect of addition of selenium to treatment regimen of hospitalized patients with COVID-19 on the outcome of disease compared with control group

Protocol summary

Study aim

Increase the chances of recovery, reduce death, and reduce the need for intensive care and mechanical ventilation by adding injectable selenium to the treatment regimen of patients with 19-year-old inpatients.

Design

At Sabzevar Vasei Hospital Medical Center, patients with 19-year-old patients with a diagnosis based on pulmonary CT scan or PCR are being examined. If the patient would have indication to be hospitalized for more than 24 hours, after obtaining informed consent from the patient, they are randomly assigned to the control and intervention group. Based on the latest Corona Protocol, the routine treatment control group includes antiretroviral therapy and, if indicated, antibiotic therapy. Receipts are given. The first day and then 500 micrograms every 12 days from the second day onwards.

Settings and conduct

At Sabzevar Vasei Hospital Medical Center, patients with 19-year-old patients with a diagnosis based on pulmonary CT scan or PCR are being examined.

Participants/Inclusion and exclusion criteria

Patients with COVID-19 who have been diagnosed based on lung imaging evidence or PCR of results of the pharyngeal mucosa will be enrolled. Patients will be excluded from the study if they are under mechanical ventilation when entering the study.

Intervention groups

In the intervention group until discharge, in addition to antiviral treatments according to the national protocol, the injected selenium will be prescribed 1000 micrograms every 12 hours on the first day and then 500 micrograms every 12 days from the second day.

Main outcome variables

The need for hospitalization in the intensive care unit, the need for mechanical ventilation, the number of

hospital days and the outcome of treatment (death / discharge)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160706028815N5**

Registration date: **2020-05-05, 1399/02/16**

Registration timing: **prospective**

Last update: **2020-05-05, 1399/02/16**

Update count: **0**

Registration date

2020-05-05, 1399/02/16

Registrant information

Name

Seyed Alireza Javadinia

Name of organization / entity

Department of Oncology, Omid Hospital, Mashhad
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2736

Email address

javadiniaa941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-20, 1399/02/31

Expected recruitment end date

2020-07-30, 1399/05/09

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of addition of selenium to treatment regimen of hospitalized patients with COVID-19 on the outcome of disease compared with control group

Public title
The effect of addition of selenium to treatment regimen of hospitalized patients with corona on the outcome of disease compared with control group

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
COVID-19 patient Presence of COVID-19 infection in the lung imaging COVID-19 PCR positive patients Age more than 18 years old
Exclusion criteria:
Mechanical ventilation

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into two groups using a simple random method (table of random numbers). To produce table of random numbers, we will use <https://www.random.org> with a range of numbers 1-40 (equal to sample size). Then after, patients will enroll to the study based on their referral/visit considering the table of random numbers.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee

Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences

Street address
Tohid Shahr BLV.

City
Sabzevar

Province
Razavi Khorasan

Postal code
9617747431

Approval date
2020-04-19, 1399/01/31

Ethics committee reference number
IR.MEDSAB.REC.1399.017

Health conditions studied

1
Description of health condition studied
COVID-19 treatment

ICD-10 code
B97.29

ICD-10 code description
Coronavirus disease (covid-19)

Primary outcomes

1
Description
Need mechanical ventilation

Timepoint
during hospitalization

Method of measurement
daily visit

2
Description
Need to be hospitalized in the intensive care unit

Timepoint
during hospitalization

Method of measurement
daily visit

3
Description
Duration of hospitalization

Timepoint
during hospitalization

Method of measurement
daily visit

Secondary outcomes
empty

Intervention groups

1

Description

Intervention group: Intervention group until discharge, in addition to antiviral treatments according to the national protocol, injectable selenium will be prescribed in the form of 1000 micrograms every 12 hours on the first day and then 500 micrograms every 12 days from the second day onwards.

Category

Treatment - Drugs

2

Description

Control group: the control group until discharge will receive antiviral treatments according to the national protocol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei Educational and Medical Center

Full name of responsible person

Afsaneh Kaffash

Street address

Vasei hospital , Shohadaye Hasteii Blvd

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Email

vasei.h@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fereshteh Ghorat

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GhoratF@medsab.ac.ir

Grant name

The effect of addition of selenium to treatment regimen of hospitalized patients with COVID-19 on the outcome of disease compared with control group

Grant code / Reference number

99008

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Afsaneh Kaffash

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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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

Clinical information (including therapeutic outcomes), laboratory and demographic of Coronavirus patients 2019 under treatment with routine and selenium

When the data will become available and for how long

About 5 to 10 months after the start of the study

To whom data/document is available

Public

Under which criteria data/document could be used

Careful study information can be provided to qualified researchers interested in treating patients.

From where data/document is obtainable

Corresponding author

What processes are involved for a request to access data/document

Competent and enthusiastic researchers can receive data documentation from the responsible author after presenting the work by presenting their academic information and identification.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Afsaneh Kaffash

Position

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Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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