Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of the effectiveness of selenium added to intravenous nutrition therapy on mortality and duration of ICU hospitalization in patients with COVID-19 disease

Protocol summary

Study aim
Evaluation of the effectiveness of selenium in mortality and duration of ICU hospitalization in patients with mechanical ventilation with COVID-19 at Nekouei Hospital

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, on 80 patients. For randomization four cards that are in the bag will be used.

Settings and conduct
ICU Department of nekooie hedayati Forghani Hospital, Qom University of Medical Sciences, Patients were divided into control and case groups, and at the end of the study The prescribing physician does not know if group one is treatment or group two

Participants/Inclusion and exclusion criteria
Inclusion criteria:Patients diagnosed with Covid-19 disease by infectious disease physician; Patients who are hospitalized in the intensive care unit and three days have passed since their hospitalization; Patients who are intubated and connected to the ventilator. Non-inclusion: Patients with COVID 19 but not Intubation

Intervention groups
Intervention group: Selenium 1 mg at the beginning and 500 micrograms daily will be prescribed during 15 minutes at 2 PM every day for 5 days. Control group: In the control group, only routine drugs are given.

Main outcome variables
Duration of hospitalization; mortality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160919029870N3**
Registration date: **2020-11-24, 1399/09/04**
Registration timing: **retrospective**

Last update: **2020-11-24, 1399/09/04**
Update count: **0**

Registration date
2020-11-24, 1399/09/04

Registrant information

Name
Reza Heydarifar

Name of organization / entity
Baqiyatallah University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 912 748 3621

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-20, 1399/01/01

Expected recruitment end date
2020-06-20, 1399/03/31

Actual recruitment start date
2020-03-20, 1399/01/01

Actual recruitment end date
2020-06-20, 1399/03/31

Trial completion date
2020-06-20, 1399/03/31

Scientific title
Evaluation of the effectiveness of selenium added to intravenous nutrition therapy on mortality and duration of ICU hospitalization in patients with COVID-19 disease

Public title

The effect of selenium in patients with Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with Covid-19 disease by infectious disease physician Patients who are hospitalized in the special ward and three days have been passed since their hospitalization Patients who are intubated and connected to a ventilator

Exclusion criteria:

Patients with covid-19 who are not intubated.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed using block randomization with blocks of size 4. All four modes: AABB, ABAB, BBAA, BABA are written on four cards, and four patients are randomly allocated to groups, respectively. The ward's head takes the card out of the bag, and the patients are divided into groups by chance. For example, if the card is AABB, the first and second patients are in the first group, and the third and fourth patients are in the second group, and also for the next four patients, another card will be drawn.

Blinding (investigator's opinion)

Double blinded

Blinding description

Since patients have no knowledge of the drug, they were blinded in this study. The researcher is unaware of the grouping of drugs, and after statistical analysis, it is determined that group A was the treatment group and group B was the control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

Clinical Research Unit; Nekouei hospital; Shahid Delazar street

City

Qom

Province

Ghoum

Postal code

3714935455

Approval date

2020-03-16, 1398/12/26

Ethics committee reference number

IR.MUQ.REC.1398.161

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Duration of hospitalization

Timepoint

The first day of patients' arrival and the day of discharge from the ICU or death of patients

Method of measurement

Number of days patients are admitted to the ICU

Secondary outcomes

1

Description

Death

Timepoint

Daily from the day of admission to the special ward until discharge or death of patients

Method of measurement

Document

Intervention groups

1

Description

Intervention group: according to the protocol, in this group, one mg of selenium in the form of stat (initial dose and amount) and 500 micrograms of intravenous infusion for 15 minutes at 2 pm every day are

administrated by an anesthesiologist for five days.

Category

Treatment - Drugs

2

Description

Control group: Routine procedures are performed on a patient with confirmed COVID-19.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Nekouei Hedayati Forqani Hospital, Qom

Full name of responsible person

Hamed Shafiee

Street address

Clinical Research Unit; Nekouei hospital; Shahid Delazar street

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Qom 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

Ghoum University of Medical Sciences

Full name of responsible person

Hamed Shafiee

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Position

Assistant Professor

Latest degree

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Person responsible for updating data

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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
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
When the data will become available and for how long
.
To whom data/document is available
.
Under which criteria data/document could be used
.
From where data/document is obtainable
What processes are involved for a request to access data/document
Comments