

# 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)

###### Phone

+98 912 748 3621

###### Email address

rheidarifar@muq.ac.ir

##### 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

Ghous

## 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**

Qom

**Province**

Ghous

**Postal code**

3714935455

**Phone**

+98 25 3133 1602

**Email**

rheidarifar@muq.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ghous University of Medical Sciences

**Full name of responsible person**

Hamed Shafiee

**Street address**

Clinical Research Unit; Nekouei hospital; Shahid Delazar street

**City**

Qom

**Province**

Ghous

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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**

Ghous University of Medical Sciences

**Full name of responsible person**

Hamed Shafiee

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Clinical Research Unit; Nekouei hospital; Shahid Delazar street

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ghoum University of Medical Sciences

**Full name of responsible person**  
Hamed Shafiee

**Position**  
Assistant Professor

**Latest degree**  
Specialist

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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