

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of combination of selenium, vitamin C and methylprednisolone in acute respiratory distress syndrome mortality and morbidity from COVID-19

#### Protocol summary

##### Study aim

The effect of selenium, vitamin C and methylprednisolone combination in mortality and morbidity of Covid-19 patients.

##### Design

A simple randomized, double-blind, placebo-controlled clinical trial. Clinical observers, outcome assessors and data analysts are blind.

##### Settings and conduct

Patients with Covid-19 admitted to the ICU of Sina Hospital in Tabriz will be included. Patients are randomly assigned to two groups. In the intervention group, a combination of selenium, vitamin C and methylprednisolone, and in the control group, only routine intensive care unit treatments based on the national protocol will be used to compare the effects of this combination in mortality and morbidity of acute respiratory distress syndrome caused by covid-19 in these patients. In this study, evaluator, and researcher are blinded to the study. Only the nurse or specialist providing the intervention (therapist) is aware of the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Positive PCR test for Covid-19. Diffuse asymmetric pulmonary involvement on CT scan. Absence of evidence of liquid overload. Covid-19 ARDS due to Berlin criteria. Exclusion criteria: Corticosteroid history in the past 3 months. Sensitivity to vitamin C. Increased sensitivity to selenium. Primary creatinine above 1.5. Ethylene glycol poisoning.

##### Intervention groups

Intervention group: This group underwent routine treatments in the intensive care unit according to the national protocol for Covid-19 patients plus cocktail therapy of 1 mg daily intravenous selenium, 60 mg / kg / d vitamin C and 1 mg / kg / d one hour infusion of methylprednisolone for 7 days. And in the control group,

only routine treatments of the intensive care unit will be provided according to the national protocol.

##### Main outcome variables

Days of hospitalization in ICU, mortality, duration of mechanical ventilation, days of hospitalization.

#### General information

##### Reason for update

##### Acronym

covid-19

##### IRCT registration information

IRCT registration number: **IRCT20190312043030N2**

Registration date: **2020-08-19, 1399/05/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-08-19, 1399/05/29**

Update count: **0**

##### Registration date

2020-08-19, 1399/05/29

##### Registrant information

##### Name

seied hadi saghaleini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 1994

##### Email address

saghaleinih@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-29, 1399/04/09

##### Expected recruitment end date

2020-10-30, 1399/08/09

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The effect of combination of selenium, vitamin C and methylprednisolone in acute respiratory distress syndrome mortality and morbidity from COVID-19

**Public title**  
The effect of selenium, vitamin C and methylprednisolone combination on mortality and morbidity of Covid-19 patients.

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Positive PCR test for Covid 19 Diffuse asymmetric pulmonary involvement on CT scan complies with Covid-19 Absence of evidence of liquid overload. PaO<sub>2</sub>/FiO<sub>2</sub> ratio ≤300 and >200 is mild ARDS; PaO<sub>2</sub>/FiO<sub>2</sub> ratio 100-200 is moderate ARDS; PaO<sub>2</sub>/FiO<sub>2</sub> ratio <100 is severe ARDS new/worsening respiratory symptoms within 1 week  
**Exclusion criteria:**  
Corticosteroid history over the past 3 months Sensitivity to vitamin C. Increased sensitivity to selenium. Primary creatinine above 1.5. Ethylene glycol poisoning.

**Age**  
From **18 years** old to **90 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Care provider
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
We will construct 6 blocks in AABB, BBAA, ABAB, BABA, ABBA and BAAB using four blocks. We will assign 1 to 6 for each block. Then, using the random number table, based on the sample size, 10 units of 4 blocks will be selected so that we consider having 20 people in control group (A) and 20 people in intervention group (B). Therefore, we will do block randomization.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this study, clinical caregivers, outcome assessor and data analyzer will not know about grouping. Outcome assessor and data analyst are blind in this study thus the findings are related to groups A and B in the study

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

##### Street address

Vice chancellor for research, Golgasht Street

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5183915881

#### Approval date

2020-06-29, 1399/04/09

#### Ethics committee reference number

IR.TBZMED.REC.1399.340

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19

## Primary outcomes

### 1

#### Description

Days of hospitalization in ICU.

#### Timepoint

From the time of the patient's arrival until the diagnosis of ICU.

#### Method of measurement

According to the number of days the patient was hospitalized in the ICU.

### 2

#### Description

Mortality

#### Timepoint

From the beginning of the interventions to 5 days after the end of the interventions.

**Method of measurement**

Mortality census based on patients recorded information

**3****Description**

Duration of mechanical ventilation.

**Timepoint**

From the time the patient enters the ICU until discharge from this ward.

**Method of measurement**

Number of days the patient is under mechanical ventilation based on patients recorded information

**4****Description**

Days of hospitalization.

**Timepoint**

From initial admission to hospital discharge.

**Method of measurement**

Number of days of patient attendance from initial admission to hospital discharge based on patients recorded information

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Control group: This group undergoing only routine treatments of the intensive care unit will be provided according to the national protocol that include tablet hydroxychloroquine and tablet lupinavir/ritonavir for 14 days and supportive care in ICU

**Category**

Prevention

**2****Description**

Intervention group: This group underwent routine treatments in the intensive care unit according to the national protocol for Covid 19 patients plus cocktail therapy of 1 mg daily intravenous selenium, 60 mg / kg / d vitamin C and 1 mg / kg / d one hour infusion of methylprednisolone for 7 days

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Sina Hospital

**Full name of responsible person**

Dr.Seied Hadi Saghaleini

**Street address**

Sina Hospital , Azadi street ,Tabriz

**City**

Tabriz

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East Azarbaijan

**Postal code**

5163639888

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**Email**

hsaghaleini@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Abolghasem Joyban

**Street address**

Vice chancellor for research, Daneshgah street, Tabriz

**City**

Tabriz

**Province**

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**Email**

research-vice@tbzmed.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Seied Hadi Saghaleini

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Sina Hospital , Azadi street ,Tabriz

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Tabriz

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**Position**

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Seied Hadi Saghaleini

**Position****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**

All potential data can be shared after making peoples unrecognizable.

**When the data will become available and for how long**

Starting 6 months after publication

**To whom data/document is available**

Documents will be available for people working in academic institutions and also people working in businesses.

**Under which criteria data/document could be used**

There will be no specific limitations to the utilization of the data

**From where data/document is obtainable**

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

Applicants will access the data from the present study by sending an email to the responsible author for a maximum of one week.

**Comments**