Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Feb 2023

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. PaO2/FiO2 ratio ≤300 and >200 is mild ARDS; PaO2/FiO2 ratio100-200 is moderate ARDS; PaO2/FiO2 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz 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?
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
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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
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
Dr .Seyed Hadi Saghaleini Sina Hospital Azadi Street, Sina Hospital, Tabriz East Azarbaijan Islamic Republic of Iran Phone+98 41 35412101 Fax+98 41 35412101 hsaghaleini@gmail.com
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