Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Sep 2021

The effect of vitamin C and E in the treatment and clinical course of patients with SARS-cov2 (COVID-19)

Protocol summary

Study aim
The effect of vitamin C and E in the treatment and clinical course of patients with SARS-cov2(COVID-19)

Design
Clinical trial with control group, with parallel, randomized groups, phase 2-3 on 80 patients. The Random Sample of Cases menu of spss software was used for randomization.

Settings and conduct
At Amin Hospital in Isfahan, 80 patients with COVID-19 were selected and the demographic and clinical information of the subjects included, including age, sex, initial diagnosis (cause of hospitalization), underlying disease, WBC count, ESR and CRP and LDH levels, CT scan Lung and RT PCR will be recorded for all patients prior to hospitalization. The diagnostic criterion for COVID-19 in patients to enter the study is pulmonary involvement in CT scan of the lung with RT PCR test.

Participants/Inclusion and exclusion criteria
Inclusion: 18 years of age or older, Diagnosis of COVID-19 by RT PCR and CT scan of the lungs, Blood oxygen levels are between 90 and 93 percent, Breathing rate between 20 and 24 per minute, Heart rate between 100 and 130 beats per minute, Exclusion: Intubation (mechanical ventilation), Allergic reaction to drugs, Shortness of breath caused by cardiogenic pulmonary edema, Pregnancy and lactation, History of oxygen therapy at home, Patients with end stage, lung, malignant, G6PD deficiency, diabetic, ketoacidosis, cardiac arrhythmia.

Intervention groups
The control group included 40 patients with Qovid-19 who took hydroxychloroquine sulfate tablets with Lupinavir / Ritonavir tablets 200/50 mg every 12 hours, 2 pills, or 400 mg of hydroxychloroquine diet on the first day and then 200 mg every 12 hours. , will be given. For the test group (40 people), in addition to the above, 1 gram of oral vitamin C and 400 units of oral vitamin E will be prescribed daily during the patient's hospital stay.

Main outcome variables
Clinical response; Mortality; hospital stay

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180425039414N3**
Registration date: **2020-06-17, 1399/03/28**
Registration timing: **retrospective**

Last update: **2020-06-17, 1399/03/28**
Update count: **0**

Registration date
2020-06-17, 1399/03/28

Registrant information
Name
Atousa Hakamifard
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3668 5555
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-04-20, 1399/02/01
Expected recruitment end date
2020-05-21, 1399/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of vitamin C and E in the treatment and clinical course of patients with SARS-cov2 (COVID-19)

Public title
The effect of vitamin C and E in the treatment and clinical course of patients with SARS-cov2 (COVID-19)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
18 years of age or older Diagnosis of COVID-19 by RT PCR and CT scan of the lungs Blood oxygen levels are between 90 and 93 percent Breathing rate between 20 and 24 per minute Heart rate between 100 and 130 beats per minute

Exclusion criteria:
Intubation (mechanical ventilation) Shortness of breath caused by cardiogenic pulmonary edema Pregnancy and lactation Patients with end stage, lung, malignant, G6PD deficiency, diabetic ketoacidosis, cardiac arrhythmia

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
80 patients with Qovid-19who had a case file in the hospital registration system and inclusion criteria, were selected available, consecutively, until the sample size was completed. The patients are then randomly assigned to the two groups of intervention and control (randomly using Block Randomization by four blocks)

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Isfahan University of Medical Sciences, Hezar Jarib Street.

City
Isfahan

Province
Isfehan

Postal code
7346181746

Approval date
2020-04-16, 1399/01/28

Ethics committee reference number
IR.MUI.MED.REC.1399.047

Health conditions studied

1

Description of health condition studied
SARS-cov2(COVID-19)

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Clinical response

Timepoint
During hospitalizatio

Method of measurement
Cessation of fever, improvement of shortness of breath, reduction of cough, blood oxygenation (SaO2) and hemodynamic parameters

2

Description
Mortality

Timepoint
During hospitalizatio

Method of measurement
Count the number of dead patients

3

Description
Hospital stay

Timepoint
During hospitalizatio

Method of measurement
Count the number of hospital days to improve clinical symptoms

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Includes 40 patients with COVID-19 for 5 days, hydroxychloroquine sulfate tablets with lopinavir / ritonavir tablets of 200/50 mg, 2 tablets every 12 hours, or 400 mg hydroxychloroquine diet on the first day and then 200 mg. It will be given every 12 hours. In addition to the above, 1 gram of oral vitamin C and 400 units of oral vitamin E will be prescribed daily during the patient's hospital stay.
Category
Treatment - Drugs

2

Description
Control group: Includes 40 patients with COVID-19 for 5 days, hydroxychloroquine sulfate tablets with lopinavir / ritonavir tablets of 200/50 mg, 2 tablets every 12 hours, or 400 mg hydroxychloroquine diet on the first day and then 200 mg. It will be given every 12 hours.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amin Hospital
Full name of responsible person
Atousa Hakamifard
Street address
Shohadas' Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shghayegh Haghjoo Javanmard
Street address
Isfahan University Of Medical Sciences, Hezar Jarib Ave
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Postal code
8174673461
Phone
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Email
sh_haghjoo@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Atousa Hakamifard
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
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Person responsible for scientific inquiries

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Full name of responsible person

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Position
Assistant professor

Latest degree
Specialist

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Person responsible for updating data

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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 information can be shared two months after the results are published.

When the data will become available and for how long
Two months after the results are published.

To whom data/document is available
Doctors, nurses, and infectious disease specialists

Under which criteria data/document could be used
To evaluate other complementary therapies and compare their effects with existing COVID-19 therapy

From where data/document is obtainable
Send email to a.hakamifard@med.mui.ac.ir

What processes are involved for a request to access data/document
Two months after the publication of the results, send your email to a.hakamifard@med.mui.ac.ir and write your request clearly. In this case, and finally within a month after receiving the email and the above will be answered

Comments