

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

Email address

a.hakamifard@med.mui.ac.ir

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-19 who 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

Isfahan

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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8174675731

Phone

+98 31 3668 5555

Email

a.hakamifard@med.mui.ac.ir

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

City

Isfahan

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Postal code

8174673461

Phone

+98 31 3668 0042

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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Alzahra hospital, Sofeh Ave.

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Email

a.hakamifard@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Atousa Hakamifard

Position

Assistant professor

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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

Person responsible for updating data

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

Street address

Alzahra hospital, Soffeh Ave

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