

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### 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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

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

##### Province

Isfahan

##### 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

##### Street address

Alzahra hospital, Sofeh Ave.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

۷۳۴۶۱-۸۱۷۴۶

##### Phone

+98 31 3668 5555

##### Fax

##### 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

**Latest degree**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Atousa Hakamifard

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**Email**

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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**