# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Jul 2026

## The effectiveness of dietary supplements containing antioxidant compounds on survival rate of patients with COVID-19

### Protocol summary

**Study aim**
Evaluation of the effectiveness of the new formulation of antioxidant dietary supplement on the outcome (duration of discharge and death) of COVID-19 patients

**Design**
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 50 patients. Balance block randomization method was used for randomization.

**Settings and conduct**
This study will be performed in two groups of patients (non-critical :) with Covid-19 disease (group receiving complementary therapy and receiving placebo) in Bu Ali Hospital (special isolation ward and corona emergency department that are in accordance with the treatment protocol). Took.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Positive coronavirus pharyngeal PCR test, involvement in CT lung scan. Oxygen level, sub-cough symptoms, sore throat, headache, nasal congestion, fever, body aches and pains, fatigue
Exclusion criteria: Bacterial respiratory infections, serious chronic diseases, pregnant women with HIV, cancer, vascular disease, or endocrine disease that have required dose adjustment in the past 30 days. Also patients who become infected while studying.

**Intervention groups**
1- Placebo receiving group 2- Antioxidant supplement therapy group: (Formulation containing melatonin, acetylcysteine, vitamin C, vitamin E, glutathione, selenium and zinc)

**Main outcome variables**
Vital respiratory symptoms of patients, hours with fever as well as fibrinogen and di-dimer levels, ROS as well as laboratory indicators, corona virus loading rate, duration of possible need for use of mechanical lung ventilation systems, survival rate (duration of discharge and death, and 28-day death) patients

### General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20160625028622N2**
Registration date: **2022-01-16, 1400/10/26**
Registration timing: **prospective**

Last update: **2022-01-16, 1400/10/26**
Update count: **0**

**Registration date**
2022-01-16, 1400/10/26

**Registrant information**

**Name**
Ehsan Aali

**Name of organization / entity**
Qazvin University of Medical Sciences

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-01-20, 1400/10/30

**Expected recruitment end date**
2022-06-19, 1401/03/29

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effectiveness of dietary supplements containing antioxidant compounds on survival rate of patients with COVID-19

**Public title**
survey on the effect of antioxidant supplement on improvement of different symptom in covid-19 patient

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
A positive PCR test for a new coronavirus Having an involvement in a CT scan of the lungs and a definitive diagnosis by the treating physician that the person is infected Therefore, people whose confirmed results of this virus are confirmed and who have 2 or more of the following symptoms will be studied in the following study: Including: Patients with pulmonary involvement of 50% and above (severe cases) (sometimes closed At the discretion of the physician and the patient's condition, lower lung involvement is also a criterion for hospitalization (moderate cases), 90 <O2 saturation <94 (moderate to severe cases) and o2 saturation <90 (severe cases), sub-cough symptoms (visual assessment criteria) Sore throat (patient report), headache (patient report), nasal congestion (patient report), fever (temperature above 37.3), body aches and pains (patient report), fatigue (patient report)

**Exclusion criteria:**
Patients suspected of having a bacterial respiratory infection at the beginning of the study Patients with serious chronic diseases. Pregnant women Patients with HIV Patients with cancer Patients with vascular disease Patient with endocrine disease Patients who become infected during studying

**Age**
From **18 years** old to **70 years** old

**Gender**
Both

**Phase**
2

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **50**

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

**Randomization description**
Patients are assigned to two treatment groups A and B using the balance block method (Balance block randomization), the size of each block is 10 and the total number of blocks is 5 as described in the attached table. block identifier block size sequence within block treatment 1 10 1 Group B 1 10 2 Group B 1 10 3 Group B 1 10 4 Group B 1 10 5 Group A 1 10 6 Group A 1 10 7 Group A 1 10 8 Group A 1 10 9 Group A 1 10 10 Group B 2 10 1 Group B 2 10 2 Group A 2 10 3 Group A 2 10 4 Group A 2 10 5 Group B 2 10 6 Group A 2 10 7 Group B 2 10 8 Group A 2 10 9 Group B 2 10 10 Group B 3 10 1 Group A 3 10 2 Group A 3 10 3 Group B 3 10 4 Group B 3 10 5 Group A 3 10 6 Group A 3 10 7 Group A 3 10 8 Group B 3 10 9 Group B 3 10 10 Group B 4 10 1 Group A 4 10 2 Group A 4 10 3 Group A 4 10 4 Group B 4 10 5 Group B 4 10 6 Group A 4 10 7 Group B 4 10 8 Group A 4 10 9 Group B 4 10 10 Group B 5 10 1 Group B 5 10 2 Group B 5 10 3 Group B 5 10 4 Group A 5 10 5 Group A 5 10 6 Group A 5 10 7 Group B 5 10 8 Group B 5 10 9 Group A 5 10 10 Group A

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

**Blinding description**
Complementary therapy and placebo are delivered to the hospital doctor in two cans of medicine with different codes. The doctor does not know the contents of these cans and only based on the defined codes, the researcher informed them.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Ǭazvin University of Medical Sciences

**Street address**
Bahonar street, qazvin university of medical science

**City**
qazvin

**Postal code**
3419759811

**Approval date**
2021-12-18, 1400/09/27

**Ethics committee reference number**
IR.QUMS.REC.1400.365

## Health conditions studied

### 1

**Description of health condition studied**
Covid-19

**ICD-10 code**
U07.1

**ICD-10 code description**
COVID-19, virus identified

## Primary outcomes

**1**

**Description**
Cough
**Timepoint**
At the beginning of the study, 14 and 28 days
**Method of measurement**
frequency and severity

**2**

**Description**
chest pain
**Timepoint**
At the beginning of the study, 14 days
**Method of measurement**
presence or absence

**3**

**Description**
shortness of breath
**Timepoint**
At the beginning of the study, 14 days
**Method of measurement**
presence or absence

**4**

**Description**
O2 saturation level
**Timepoint**
At the beginning of the study, 14 days
**Method of measurement**
Oxygen level (O2 Saturation) with device

**5**

**Description**
number of days with tachypnea
**Timepoint**
At the beginning of the study, 14 days
**Method of measurement**
Breathe more than 12-20 times a minute

**6**

**Description**
fever
**Timepoint**
At the beginning of the study, 14 days
**Method of measurement**
Temperatures above 37.3, with an accuracy of 6 hours

**7**

**Description**
fibrinogen levels
**Timepoint**
At the beginning of the study, 14 days
**Method of measurement**
Diagnostic laboratory

**8**

**Description**
di-dimer
**Timepoint**
At the beginning of the study, 14 days
**Method of measurement**
Diagnostic laboratory

**9**

**Description**
ROS
**Timepoint**
At the beginning of the study, 14 days
**Method of measurement**
Diagnostic laboratory

**10**

**Description**
laboratory indicators
**Timepoint**
At the beginning of the study, 14 days
**Method of measurement**
Diagnostic laboratory

**11**

**Description**
duration of possible need for use of mechanical lung ventilation systems
**Timepoint**
At the beginning of the study, 14 days
**Method of measurement**
Duration of possible need for use of mechanical lung ventilation systems

**12**

**Description**
survival rate of patients
**Timepoint**
At the beginning of the study, 14 and 28 days
**Method of measurement**
Duration of clearance and mortality 28 days

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Antioxidant supplement,Antioxidant supplement, this study is a clinical trial study. Initially, capsules containing defined doses of antioxidant compounds are formulated with the formulation and based on related studies in a pharmaceutical laboratory located in Tehran province, a pharmacologist prepares, manufactures and quality controls. This capsule contains 250 mg of vitamin C, 300

mg of N-acetylcysteine, 2.5 mg of melatonin, 100 mg of selenium, 200 mg of glutathione and 60 mg of vitamin E and 5 mg of zinc. These supplements are purchased commercially from reputable companies active in this field in higher quantities by calculating the required amount according to their defined formulation and taking into account the number of patients, and the capsules are prepared, packaged and prepared in the pharmaceutical company. Target groups will receive two supplements / placebo on the first day and one every day for 10 days in the coming days. First, the informed consent form will be delivered to all patients and written consent will be obtained from them.

**Category**

Treatment - Drugs

**2**

**Description**

Placebo,Placebo, this group of patients with Covid 19 (Non-Critical) who will receive routine drugs of the country's treatment protocol and will receive two placebo on the first day and one every day for 10 days in the coming days. Patients will be imaged before treatment begins.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Buali hospital of Qazvin
**Full name of responsible person**
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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Qazvin University of Medical Sciences
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Vice President for Research and Technology
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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**

Qazvin 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**
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Dr Ehsan Aali
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available