Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Qazvin University of Medical Sciences
Full name of responsible person
Dr Ehsan Aali
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Associate professor
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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