

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of microalga *Spirulina platensis* supplement on the recovery of patients with coronavirus hospitalized in the coronavirus ward and reduction of mortality due to the disease.

#### Protocol summary

##### Study aim

The effect of spirulina platensis supplementation on disease severity and mortality in patients with coronavirus.

##### Design

This clinical trial has parallel intervention and control group, open-label, randomized, multicenter, phase 3 on 240 patients. Random Allocation Software was used for randomization.

##### Settings and conduct

The present study is an open-label clinical trial. The target population is patients hospitalized in the coronavirus ward of Ziaeian Hospital and Baharloo Hospital.

##### Participants/Inclusion and exclusion criteria

Patients with coronavirus. Inclusion criteria 1- Male and female patients, age  $\geq 18$ . 2- The patient is stable in condition and does not need resuscitation. 3- Signed informed consent form. 4- Definitive/clinical diagnosis of coronavirus. ... Exclusion criteria 1- Pregnancy or lactation. 2- Any history of drug allergy. 3- Active, clinically significant chronic illness or human immunodeficiency virus disease. 4- Significant organ dysfunctions such as renal failure, liver dysfunction, CHF, or serious and unstable cardiac condition. ...

##### Intervention groups

Based on the entry criteria, patients who are eligible to enter the study are randomly divided into two intervention and control groups using the block randomization method. After obtaining consent from the patients, the intervention group will receive 15/2 g spirulina platensis algae powder daily.

##### Main outcome variables

Reducing the severity of the disease and its mortality.

#### General information

##### Reason for update

Due to the patients' negative attitude towards the placebo and their non-participation, the placebo was removed. The study method was changed from single-blind to open-label. After changing the study method, the new sample size was calculated.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210216050373N1**  
Registration date: **2021-05-28, 1400/03/07**  
Registration timing: **registered\_while\_recruiting**

Last update: **2023-02-13, 1401/11/24**

Update count: **1**

##### Registration date

2021-05-28, 1400/03/07

##### Registrant information

###### Name

Seyed ahmad Seyed alinaghi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6658 1583

###### Email address

s\_a\_alinaghi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-03, 1399/12/13

##### Expected recruitment end date

2022-03-04, 1400/12/13

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The effect of microalga Spirulina platensis supplement on the recovery of patients with coronavirus hospitalized in the coronavirus ward and reduction of mortality due to the disease.

**Public title**  
The effect of Spirulina platensis supplement in the treatment of coronavirus

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Male and female patients, age  $\geq 18$ . The patient is stable in condition and does not need resuscitation. Signed informed consent form. Definitive/clinical diagnosis of coronavirus. The same treatment protocol (coronavirus) in both groups. oxygen saturation  $\leq 94\%$ .  
**Exclusion criteria:**  
Pregnancy or lactation. Any history of drug allergy. Active, clinically significant chronic illness or human immunodeficiency virus disease. Significant organ dysfunctions such as renal failure, liver dysfunction, CHF, or serious and unstable cardiac condition. Underlying conditions that can affect patients' ability to provide adequate data. Inability or refusal to sign the informed consent. Any concurrent diseases or conditions which delay wound healing (cancer, vasculitis, immunosuppressive disorders, etc.) Treatment with corticosteroids, Treatment with blood thinners (Warfarin), immunosuppressants, radiotherapy, or chemotherapy. Receiving any investigational drug within 30 days prior to screening. Abnormal liver enzymes and total bilirubin  $> 1.5$  times of normal upper limit. Specific and rare diseases such as people with HIV who are not receiving antiretroviral treatment, multiple sclerosis, SLE, rheumatoid arthritis, and PKU. Observation of clinical signs not previously seen in patients with coronavirus and unusual complaints from patients. Severe nausea after taking medication that does not improve with routine supportive treatment is considered as an exclusion criterion.

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **240**  
More than 1 sample in each individual  
Number of samples in each individual: **4**  
Each patient will be sampled four times, on the first day, the third day, the fifth day, and the seventh day.

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

Randomized

## **Randomization description**

At the beginning of the patient's hospitalization before the start of the study, patient demographic information is recorded about the history of specific diseases and related to anthropometrics and current disease conditions. Patients who are eligible for inclusion based on the inclusion criteria, randomly with the block randomization method, are placed in two groups of intervention and control. In our study, due to changing the study method from single-blind to open-label, random blocks of variable size will be used to avoid revealing the last allocation in each block.

## **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 Imam khomeini Hospital  
Complex- Tehran University of Medical Sciences

##### **Street address**

Imam Khomeini Hospital Complex, Tohid Square,  
Tehran, Iran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1419733141

#### **Approval date**

2021-02-17, 1399/11/29

#### **Ethics committee reference number**

IR.TUMS.IKHC.REC.1399.481

## **Health conditions studied**

### 1

#### **Description of health condition studied**

COVID-19

#### **ICD-10 code**

U07.02

#### **ICD-10 code description**

COVID disease

## Primary outcomes

### 1

#### Description

Disease severity

#### Timepoint

The first day, the third day, the fifth day, and the seventh day are the periods of measuring the variables of our study.

#### Method of measurement

Disease severity is measured by the relevant variables: Lymphocyte count, Alanine transaminase, Aspartate transaminase, White Blood Cells, Erythrocyte sedimentation rate, C-Reactive Protein, Hemoglobin, Creatinine, D-Dimer, ferritin, Platelet, Lactate Dehydrogenase, Prothrombin Time, Oxygen saturation and Patient body temperature. Cytokines and chemokines levels, including IL-10, IL-6, IP-10, IFN $\gamma$ , TNF $\alpha$ , CCL2, and CCL3, are also measured by enzyme-linked immunosorbent assay (ELISA).

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: patients using spirulina platensis supplement plus standard treatment of Covid-19.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: patients receiving standard Covid-19 treatment alone.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ziaeian Hospital

##### Full name of responsible person

Dr. SaeedReza JamaliMoghadam

##### Street address

Ziaeian Hospital, opposite the municipality of the region 17, Abouzar Street, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1366736511

#### Phone

+98 21 5517 6814

#### Email

ziaeian@tums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Baharloo Hospital

##### Full name of responsible person

Dr. Hadise Hosami

##### Street address

Baharloo Hospital, Behdari St, Railway Sq, and Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

12299

##### Phone

+98 21 5565 8500

##### Email

baharloo@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. SeyedAhmad SeyedAlinaghi

##### Street address

Imam Khomeini Hospital Complex, Tohid Square, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733141

##### Phone

+98 21 6658 1583

##### Email

Imamhospital@tums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

Food Industry Company Berke Sabz Mad Asia

#### Proportion provided by this source

80

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

Industry

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Pasture Institute of Iran

#### Full name of responsible person

MohamadAli ZaheriBirgani

#### Position

Student

#### Latest degree

Master

#### Other areas of specialty/work

Medical Biotechnology

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Imam Khomeini Hospital Complex, Tohid Square,  
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Amzb11@protonmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr. SeyedAhmad SeyedAlinaghi

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Epidemiology

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s.a.alinaghi@gmail.com

## Person responsible for updating data

### Contact

#### Name of organization / entity

Pasture Institute of Iran

#### Full name of responsible person

MohamadAli ZaheriBirgani

#### Position

Student

#### Latest degree

Master

#### Other areas of specialty/work

Medical Biotechnology

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#### Postal code

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#### Phone

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#### Email

Amzb11@protonmail.com

## 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

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

The research results will be presented and published  
only in the form of reports and articles.

### When the data will become available and for how long

The access period starts 6 months after the results are  
published.

### To whom data/document is available

It will be available to researchers working in academic  
and scientific institutions.

### Under which criteria data/document could be used

Researchers for use in articles and reports, especially  
systematic review articles.

### From where data/document is obtainable

To receive the required documents or data, refer to the  
project manager, Dr. Seyed Ahmad Seyed Alinaghi, at the  
Iranian Research Center for HIV/AIDS. Phone number:  
00982166581583 Email: s.a.alinaghi@gmail.com  
Address: Iranian Research Center for HIV/AIDS, behind

the Infectious Diseases Building, Imam Khomeini Hospital Complex, end of Keshavarz Boulevard, Tehran.

**What processes are involved for a request to access data/document**

After making the call(Phone, meet, Email) and providing the necessary documents(Written request), the documents or data files will reach the applicant.

**Comments**