

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 Ziaieian Hospital and Baharloo Hospital.

Participants/Inclusion and exclusion criteria

Patients with coronavirus. Inclusion criteria 1- Male and female patients, age ≥ 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 ≥ 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 γ , TNF α , 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

Ziaeeian Hospital

Full name of responsible person

Dr. SaeedReza JamaliMoghadam

Street address

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

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1366736511

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2

Recruitment center

Name of recruitment center

Baharloo Hospital

Full name of responsible person

Dr. Hadise Hosami

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. SeyedAhmad SeyedAlinaghi

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Student

Latest degree

Master

Other areas of specialty/work

Medical Biotechnology

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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

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 Alinghi, 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