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 ≥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 ≤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, IFNγ, TNFα, 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
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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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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
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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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Contact

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Position
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Latest degree
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Person responsible for updating data

Contact

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Full name of responsible person
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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