Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

A clinical trial to compare the effectiveness of the Spirulina platensis algae (Arthrospira, blue-green algae) and N-acetyl cysteine with standard treatment in patients with COVID-19 infection

Protocol summary

Study aim

Determination of the therapeutic effect of the Spirulina platensis algae (Arthrospira, blue-green algae) and N-acetyl cysteine in patients with COVID-19 infection

Design

This randomized, phase I-II, and single-blind clinical trial with parallel and control groups will be conducted on 60 patients who will be randomly selected using the blocks.

Settings and conduct

Patients with COVID-19 infection referring to Imam Reza Hospital and Ghaem Hospital are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. Patients will receive Spirulina platensis algae + N-acetyl cysteine + standard treatment. The person responsible for data collection is blind to group allocation and the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with COVID-19 infection base on clinical manifestations, chest CT scan and PCR test results; age over 18 years; the oxygen saturation of patient is 85 percent or greater at rest. Exclusion criteria: Having chronic lung disease; pregnant women; having autoimmune disease; history of allergy to the seaweed or its derivatives; history of bronchospasm after using of N-acetylcysteine; having chronic liver disease; history of phenylketonuria; having bleeding; neutrophil count of less than 500 mmc; A platelet count of less than 2000 mmc; having acute hepatitis.

Intervention groups

The intervention group I will receive 80 mg/kg/day Spirulina platensis algae + standard treatment, the intervention group II 80 mg/kg/day Spirulina platensis algae + twice daily N-acetylcysteine 600 mg + standard treatment. The control group standard treatment.

Main outcome variables

Evaluation of the duration of hospitalization, improvement rate of clinical symptoms such as dyspnea and fever, possibility of hospitalization in ICU and Mortality rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220509054793N1**
Registration date: **2022-06-02, 1401/03/12**
Registration timing: **prospective**

Last update: **2022-08-14, 1401/05/23**
Update count: **1**

Registration date

2022-06-02, 1401/03/12

Registrant information

Name

Farid Poursadegh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3854 3031

Email address

poursadeghf@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A clinical trial to compare the effectiveness of the Spirulina platensis algae (Arthrospira, blue-green algae) and N-acetyl cysteine with standard treatment in patients with COVID-19 infection

Public title
The effectiveness of Spirulina platensis algae and N-acetyl cysteine for treatment of patients with COVID-19 infection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with COVID-19 infection base on clinical manifestations, chest CT scan and PCR test results Age over 18 years The oxygen saturation of patient is 85 percent or greater at rest
Exclusion criteria:
having chronic lung disease Pregnant women Having autoimmune disease History of allergy to the seaweed or its derivatives History of bronchospasm after using of N-acetylcysteine Having chronic liver disease History of phenylketonuria Having bleeding (Massive hemoptysis, gastrointestinal bleeding, epistaxis, purpura, ecchymosis) Neutrophil count of less than 500 mmc A platelet count of less than 2000 mmc Having acute hepatitis
Age
From **18 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use the restricted randomization method of block randomization. All blocks are the same size, and in this two-group experiment we will have 6 blocks (including 3 participants in the intervention group and 3 participants in the control group). Random allocation software software is also used to randomize random sequence production software (Random allocation software). To conceal, we use Allocation concealment, which refers to the method used to perform a random sequence on study participants, so that the assigned group is not identified before the individual is assigned. Using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients with COVID-19 infection referring to Imam Reza Hospital and Ghaem Hospital, Mashhad, Iran are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. The lids of the letter envelopes are glued and placed inside a box. The person responsible for data collection is blind to group allocation and the type of intervention. Patients will be aware of their medication. Intervention group I will receive the Spirulina platensis algae along with standard treatment, Intervention group II will receive the Spirulina platensis algae and N-acetyl cysteine along with standard treatment and control will receive standard treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9195965919
Approval date
2020-12-05, 1399/09/15
Ethics committee reference number
IR.MUMS.REC.1399.528

Health conditions studied

1

Description of health condition studied
Patients with COVID-19 infection

ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
The duration of hospitalization
Timepoint
Two weeks after intervention
Method of measurement
The number days of hospitalization

2

Description
Improvement rate of clinical symptoms such as dyspnea and fever
Timepoint
Three months weeks after intervention
Method of measurement
Based on clinical examinations

3

Description
Possibility of hospitalization in ICU
Timepoint
Two weeks after intervention
Method of measurement
Need to receive intensive care in the patient

4

Description
Mortality rate
Timepoint
One month after intervention
Method of measurement
Calculating a mortality rate

Secondary outcomes

1

Description
Acute respiratory distress syndrome rate
Timepoint
Two weeks after intervention
Method of measurement
Patient with acute respiratory distress syndrome

Intervention groups

1

Description
Intervention group I will receive 80 mg/kg/day Spirulina platensis algae along with standard treatment.
Category
Treatment - Drugs

2

Description
Intervention group II will receive 80 mg/kg/day Spirulina platensis algae and twice daily N-acetylcysteine 600 mg along with standard treatment
Category
Treatment - Drugs

3

Description
Control group will receive standard treatment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Farid Poursadegh
Street address
Imam Reza Hospital, Imam Reza Square
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9137913316
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drpoursadeghf@gmail.com

2

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
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vcresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Farid Poursadegh
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

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Subspecialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The research data obtained from the main outcomes of the study can be shared freely as 'open data'.

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

Under which criteria data/document could be used

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

From where data/document is obtainable

Farid Poursadegh provides the data analysis to the applicants via email: drpoursadeghf@gmail.com

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

Applicants can send emails to him and receive a response within a week.

Comments