

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Investigating effect of Spirulina (*Arthrospira platensis*) dietary supplementation on COVID-19 disease outcomes in patients admitted to Intensive Care Units of hospitals: phase 2 clinical trial

#### Protocol summary

##### Study aim

Main objective: to determine and comparison effect of Spirulina (*Arthrospira Platensis*) supplement on COVID-19 disease's outcomes (consisted of laboratory measures ; ventilator free days;) LOS ICU (length of stay in ICU); LOS Hospital (length of hospital stay) and mortality rate; clinical manifestations; severity and nutritional status) in patients admitted to intensive care units of hospitals during 4 weeks between intervention and control groups.

##### Design

Randomized control trial, with control group, randomization using Random Number Table, phase 2 on patients with COVID-19

##### Settings and conduct

The study will be carried out among COVID-19 patients admitted in ICU hospitals. Spirulina supplement will be taken to patients during 28 days and the outcomes will be followed.

##### Participants/Inclusion and exclusion criteria

Patients with positive PCR admitted in ICU will be included. Patients under 18 years of age; pregnant and lactating women and consumers of vitamins C and E, omega-3 and antioxidant supplements in the last 3 months; patients with severe renal failure; liver failure of the last stage (cirrhosis); uncontrolled hypertension; patients who do not have a functioning gastrointestinal tract and have not been prescribed oral or intravenous nutrition and also with drug / food allergies will be excluded in this study.

##### Intervention groups

Intervention group are COVID-19 patients with routine drugs and 5gr/day Spirulina powder. Control group without placebo and take normal therapeutic drugs.

##### Main outcome variables

IL6; ESR; CRP; O2SAT

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200720048139N1**

Registration date: **2020-11-09, 1399/08/19**

Registration timing: **prospective**

Last update: **2020-11-09, 1399/08/19**

Update count: **0**

##### Registration date

2020-11-09, 1399/08/19

##### Registrant information

##### Name

Monireh Hatami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2200 2040

##### Email address

hatami@iaups.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-21, 1399/09/01

##### Expected recruitment end date

2021-03-20, 1399/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Investigating effect of Spirulina (*Arthrospira platensis*) dietary supplementation on COVID-19 disease outcomes in patients admitted to Intensive Care Units of hospitals: phase 2 clinical trial

## Public title

Investigating effect of Spirulina dietary supplementation on COVID-19 disease outcomes in patients admitted to Intensive Care Units

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All covid-19 patients confirmed with PCR test admitted to the ICU are entered the trial

### Exclusion criteria:

Age less than 18 Women during pregnancy and lactation Consumers of supplements C, E, Omega 3, Antioxidants in the last 3 months Patients with severe renal failure Patients with liver failure last stage (cirrhosis) Patients with uncontrolled hypertension Patients who do not have a functioning gastrointestinal tract and have not been prescribed oral or intravenous nutrition Patients with drug / food allergies

## Age

From **18 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **138**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization is used to identify samples in the control or intervention group. We will put 138 small envelopes containing random numbers obtained from the table of random numbers (69 evens and 69 odds) and the consent form inside a large envelope. The even numbers belong to the intervention group and odd numbers belong to the control group. The patient (if the patient is not conscious the person in private care of the patient) is asked to take one of the envelopes and will be placed in one of the control or intervention groups based on the number taken.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

In this study, we have an intervention group and a control group. Intervention group will receive 5 grams of spirulina supplement in addition to routine medications and control group will not receive anything other than routine medications.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Islamic Azad Tehran Medical Sciences University-Pharmacy and Pharmaceutical Bran

##### Street address

Faculty of Pharmacy and Pharmaceutical Branches, Yakhchal Street, Shariati Street, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1941933111

#### Approval date

2020-06-07, 1399/03/18

#### Ethics committee reference number

IR.IAU.PS.REC.1399.063

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

U07.1

#### ICD-10 code description

بیماری کووید-19 تایید شده با تستهای آزمایشگاهی

## Primary outcomes

### 1

#### Description

IL6

#### Timepoint

The first and 28th of the study

#### Method of measurement

Blood Sample method: ELISA ; sensitivity 0.06 pg/ml

### 2

#### Description

ESR (Erythrocyte sedimentation rate)

#### Timepoint

The first and 28th of the study

#### Method of measurement

Automated Modified Westergren

### 3

#### Description

CRP

### **Timepoint**

The first and 28th of the study

### **Method of measurement**

Blood sampling- ELISA

### **4**

#### **Description**

Nutrition Status

#### **Timepoint**

the first and 28th of the study

#### **Method of measurement**

Nutric-score Questionnaire

### **5**

#### **Description**

Fever

#### **Timepoint**

Daily

#### **Method of measurement**

Digital Thermometer

### **6**

#### **Description**

O2 SATURATION

#### **Timepoint**

Duration the stay in ICU

#### **Method of measurement**

Pulse Oxymeter

## **Secondary outcomes**

### **1**

#### **Description**

Duration of Stay in ICU

#### **Timepoint**

Since the first day till end of stay in ICU

#### **Method of measurement**

OBSERVATION

### **2**

#### **Description**

Ventilator Free days

#### **Timepoint**

During the stay in ICU

#### **Method of measurement**

Observation

### **3**

#### **Description**

Mortality Rate

#### **Timepoint**

During the stay in ICU

#### **Method of measurement**

Observation

## **Intervention groups**

### **1**

#### **Description**

Intervention group: COVID-19 patients hospitalized in ICU

#### **Category**

Treatment - Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Farhikhtegan Hospital

##### **Full name of responsible person**

Mahdi Shadnoush

##### **Street address**

Hesarak, Shohadaye Hesarak Blvd

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1477899679

##### **Phone**

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##### **Fax**

+98 21 4484 5171

##### **Email**

farhikhteganhospital@gmail.com

##### **Web page address**

<http://farhikhtegan.iautmu.ac.ir>

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University

##### **Full name of responsible person**

Farshad Hashemian

##### **Street address**

Islamic Azad University, Tehran Medical Sciences,  
Shariati Street

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1916893813

##### **Phone**

+98 21 2200 6660

##### **Email**

hashemian.f@iaups.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

**Title of funding source**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Monireh Hatami

**Position**

Assistant Proffessor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mahdi Shadnoush

**Position**

Associte Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Nutrition

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**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Monireh Hatami

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Postal code**

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**Email**

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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