Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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

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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 ; sensivity 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
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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
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Islamic Azad University, Tehran Medical Sciences, Shariati Street
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1916893813
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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
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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