

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of Spirulina extract (Arthospira) on the improvement of clinical and laboratory symptoms in patients with Covid-19: Clinical Trial

Protocol summary

Study aim

Evaluation of the effectiveness of Spirulina extract (Arthospira) on the improvement of clinical and laboratory symptoms in patients with Covid-19: Clinical trial

Design

The clinical trial has two groups of 105 controls and the intervention is performed by simple double-blind randomization. Randomization using computer software is performed by a person other than the study researchers and based on the number assigned to each patient.

Settings and conduct

In Razi Hospital, Ahvaz, two groups of Covid-19 patients, 105 people each, one group receiving standard treatments and the other group receiving spirulina extract in addition to standard treatments. A double-blind study evaluating the outcome and analyzing the data does not have basic information about who is in the control group and who is in the main group and receiving the extract.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive confirmation of Covid 19 based on PCR results and approved global health clinical signs confirmed by a specialist; They are hospitalized. Patients have informed consent to enter the study. Exclusion criteria: the physician's decision not to participate in the study, the patient to be present in another clinical trial.

Intervention groups

Control group: There are patients who receive standard treatment for COVID-19 (oseltamivir, hydroxychloroquine, and lopinavir) according to the protocol of the Ministry of Health. Intervention group: There are patients who, in addition to standard treatment, receive spirulina extract at a dose of 5 mg twice a day (every 12 hours) for seven days. Spirulina

microalgae are prepared from Qeshm Microalgae Biore Refinery Company and extracted in Alborz Cell Fan Accelerator.

Main outcome variables

Primary outcome: fever, oxygen saturation, dry cough
Secondary outcome: laboratory factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200330046897N1**
Registration date: **2021-04-22, 1400/02/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-22, 1400/02/02**

Update count: **0**

Registration date

2021-04-22, 1400/02/02

Registrant information

Name

Parya Alidadiani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3241 1624

Email address

alidadp2@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-06-05, 1400/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of Spirulina extract (Arthospira) on the improvement of clinical and laboratory symptoms in patients with Covid-19: Clinical Trial

Public title

Evaluation of the effect of spirulina extract on patients with coronavirus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive confirmation of Covid 19 based on PCR results and approved global health clinical signs confirmed by a specialist; They are hospitalized. Patients have informed consent to enter the study.

Exclusion criteria:

The physician's decision not to participate in the study. The patient to be present in another clinical trial.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Using computer software with a simple randomization method by a person who is not a researcher and based on the number assigned to each patient are divided into two groups of intervention and control. I.e randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Outcome Evaluator and Data Analyzer Do not have basic information about who is in the control group and who is in the main group and the recipient of the extract.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Olum pezeshti Blvd, Ahvaz, Khuzestan Province

City

Ahvaz

Province

Khuzestan

Postal code

15794 61357

Approval date

2021-03-17, 1399/12/27

Ethics committee reference number

IR.AJUMS.REC.1399.970

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

Covid-19 infection

Primary outcomes

1

Description

fever

Timepoint

Daily monitoring from the beginning of the intervention to the end

Method of measurement

Thermometer

2

Description

Oxygen saturation

Timepoint

Daily monitoring from the beginning of the intervention to the end

Method of measurement

Pulse oximeter

3

Description

dry cough

Timepoint

Daily monitoring from the beginning of the intervention to the end

Method of measurement

Physical examination,questionnaire

4

Description

C-reactive protein (CRP)

Timepoint

The first day and the 7th day

Method of measurement

Blood sampling- ELISA

5

Description

Interleukin 6 (IL-6)

Timepoint

The first day and the 7th day

Method of measurement

Blood Sample method: ELISA ; sensivity 0.06 pg/ml

Secondary outcomes

1

Description

Duration of Stay in ICU

Timepoint

Since the first day till end of stay in ICU

Method of measurement

Observation

Intervention groups

1

Description

Control group: There are patients who receive standard treatment for COVID-19 (oseltamivir, hydroxychloroquine and lopinavir) according to the protocol of the Ministry of Health.

Category

Treatment - Drugs

2

Description

Intervention group: There are patients who, in addition to standard treatment, receive spirulina extract at a dose of 5 mg twice a day (every 12 hours) for seven days. Spirulina microalgae are prepared from Qeshm Microalgae Biore Refinery Company and extracted in Alborz Cell Fan Accelerator.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital of Ahvaz

Full name of responsible person

Dr. Farid Yosefi

Street address

Palestine St., in front of the governorate, Razi Hospital of Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3333 5935

Email

drfayo@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mahdi Ahmadi moghadam

Street address

Ahvaz Jondishapur University of Medical Sciences,Golestan Highway

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Ahvaz

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Khuzestan

Postal code

6135715794

Phone

+98 61 3373 8383

Email

Ahmadi-m@ajums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

2

Sponsor

Name of organization / entity

Paya Fan Yakht Alborz Company

Full name of responsible person

Dr.Hooman Kaghazian

Street address

No. 12, Unit 2, Corner of Shahid Arab Najafi Alley, in front of Tehran Villa Three Ways, Sattarkhan St.

City

Tehran

Province

Tehran

Postal code

1455844816

Phone

+98 21 6653 0487

Email

kaghazian@pasteur.ac.ir

Web page address

<https://celltechco.com/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Paya Fan Yakht Alborz Company

Proportion provided by this source

100

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**

Persons

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

Hakhamanesh Biotechnology

Full name of responsible person

Seyed Shahab Atashi

Position

Chairman of the Board

Latest degree

Master

Other areas of specialty/work

Medical Biotechnology

Street address

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seyedshahabatashi@gmail.com

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

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Mard

Position

full Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Golestan Hiway, Ahvaz Jondishapur University of Medical Sciences

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Alimard77@gmail.com

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

Hkhamanesh biotechnology company

Full name of responsible person

Parya Alidadiani

Position

vice chairman

Latest degree

Master

Other areas of specialty/work

Immunology

Street address

No. 12, Unit 2, Corner of Shahid Arab Najafi Alley, in front of Tehran Villa Three Ways, Sattarkhan St.

City

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Province

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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