

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of Spirulina as a nutritional supplement and drug in Covid-19 patients

#### Protocol summary

##### Study aim

Effect of Spirulina as a nutritional supplement and drug in Covid-19 patients

##### Design

clinical trial with control group , with parallel groups , double-blind , randomized , phase 2 on 100 patients. Random Allocation software was used for randomization.

##### Settings and conduct

In this study, 100 patients with positive covid-19 PCR referred to Imam Reza hospital in Tabriz was randomly admitted to one of the two groups which studied (two groups of drug and placebo). 50 patients entered the intervention group and 50 patients entered the placebo group. Patients information including age , gender , vital signs upon arrival, extent of pulmonary involvement were recorded by CT scan, underlying disease and medication used. Patients in the intervention group received 1g of Spirulina capsule 4 times daily, the control group received starch-containing capsules as a placebo. Then the patients were followed by telephone for 14 days. Participants and researchers compared the type of blinded capsule and the capsule information in a sealed envelope until the end of study. The effectiveness of the capsule in reducing clinical symptoms such as cough, fatigue and other symptoms, and the paraclinical findings as well as the possible side effects of the drug were measured.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmation of covid19 by PCR; consent to participate in the study  
Exclusion criteria: underlying disease , pregnancy , discontinuation of the drug

##### Intervention groups

50 patients received Spirulina capsule 4 times daily as an intervention group and 50 patients received a starch-containing capsule as a control group

##### Main outcome variables

Clinical symptoms (cough, fever, etc) , paraclinical

variables (wbc, IL-6, TNF) of the group receiving Spirulina and placebo in patient with COVID19 before and after the intervention

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101201005287N4**

Registration date: **2022-06-06, 1401/03/16**

Registration timing: **retrospective**

Last update: **2022-06-06, 1401/03/16**

Update count: **0**

##### Registration date

2022-06-06, 1401/03/16

##### Registrant information

##### Name

Akbar Sharifi

##### Name of organization / entity

Tabriz Medical University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1337 5449

##### Email address

asharifi@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-10, 1400/09/19

##### Expected recruitment end date

2021-12-13, 1400/09/22

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of Spirulina as a nutritional supplement and drug in Covid-19 patients

**Public title**

Spirulina in covid 19

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

confirmation of Covid19 by PCR test satisfaction to participate in the study

**Exclusion criteria:**

Having an underlying disease pregnancy stop taking the drug

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

From the patients who volunteered to participate in the study 100 people will be selected by simple random sampling. Randomization method: block Randomization unit: individual Random layers: In each block, people will be matched based on age and gender. Random Allocation tool: Random Allocation software. How to build a random sequence: Using Random Allocation software. Concealment: A random sequence created in a safe place and performed by an independent, non-independent person during the study.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is a double-blind study that evaluates the consequences in this study and patients participating in the study will be unaware of the type of supplement received. Supplements will be provided to patients by another person who has no role in completing the questionnaire. Patient will also be informed of existence of two types of supplement (Spirulina and Placebo) when obtaining consent, but will be unaware of which study group they will be placed in. The capsules are exactly the same in shape, color and size and will smell the same due to their proximity for several days.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Imam Reza hospital, Golgasht Ave

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Approval date**

2021-12-10, 1400/09/19

**Ethics committee reference number**

IR.TBZMED.REC.1400.919

**Health conditions studied****1****Description of health condition studied**

Covid19, Virus identified

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID19, Virus identified

**Primary outcomes****1****Description**

Interleukin-6 blood levels of patients before and after taking the drug

**Timepoint**

Before starting the drug and 14 days after taking the drug

**Method of measurement**

Blood sample analysis for IL-6 by ELISA in the laboratory

**Secondary outcomes****1****Description**

Serum TNF- $\alpha$  levels in patients plasma

**Timepoint**

Before starting the drug and 14 days after starting the drug

## Method of measurement

Blood sample analysis for TNF- $\alpha$  by ELIZA in the laboratory

## Intervention groups

### 1

#### Description

Intervention group: For 14 days ,patients received the Spirulina capsule(1g) prepared in Tabriz school of Pharmacy , while visiting the Imam Reza hospital from a researcher , consuming 4g daily with glass of water.

#### Category

Placebo

### 2

#### Description

Control group: Control group: For 14 days ,patients received a starch capsule(500mg) prepared in Tabriz school of Pharmacy , while visiting the Imam Reza hospital from a researcher , consuming 4g daily with glass of water.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital

##### Full name of responsible person

Akbar Sharifi

##### Street address

Imam Reza Hospital, Golgasht Ave

##### City

Tabriz

##### Province

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##### Postal code

5166614766

##### Phone

+98 41 3334 7059

##### Email

Asharifi@tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Akbar Sharifi

##### Street address

Imam Reza Hospital,Golgasht Ave

##### City

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#### Province

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#### Postal code

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#### Phone

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#### Fax

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#### Email

asharifi@tbzmed.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Akbar Sharifi

##### Position

professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Internal Medicine

##### Street address

Imam Reza Hospital,Golgasht Ave

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##### Phone

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##### Email

asharifi@tbzmrdr.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

**Full name of responsible person**

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professor

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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**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable