# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 2on 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 time 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: Conformation of covid19 by PCR; consent to participate in the study Exclusion criteria: underlying disease , pregnancy , discontinuation of the drug

**Intervention groups**
50patients received Spirulina capsule 4 time 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)

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+98 41 1337 5449

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**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 peregnancy 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 analysisfor IL-6 by ELIZA in the labratory

## Secondary outcomes

### 1

**Description**
Serum TNF-α levels in patients plasma
**Timepoint**
Before starting the drug and 14 days after starting the drug

**Method of measurement**
Blood sample analysis for TNF-α 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
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## Sponsors / Funding sources

### 1

**Sponsor**
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**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
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## Person responsible for updating data

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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