Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 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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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 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
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Imam Reza Hospital, Golgasht Ave
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Sponsors / Funding sources

1

Sponsor
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Tabriz University of Medical Sciences
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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