Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of curcumin supplementaion on clinical symptoms , acute phase reactants and inflamatory cytokines in patients with covid-19 hospitalization

Protocol summary

Study aim
The effect of curcumin supplementation on clinical symptoms, acute phase reactants and cytokine interleukin 6 in patients with new Covid-19 admitted to hospital

Design
A double-blind clinical trial study with placebo

Settings and conduct
This study is a double-blind randomized clinical trial that will be performed in Ali Asghar, Shahid Faghihi and Namazi hospitals in Shiraz. In this study, 76 eligible patients whose PCR test was positive and hospitalized will be divided into two groups of 38 using a random number table.Curcumin and placebo are made by Elixir Nano Drug Company.

Participants/Inclusion and exclusion criteria
1. They have a positive PCR test or lung involvement in the imaging 2- Inpatients who are non -intubated 3- They are obove18 years old 4- They have filled in the informed consent form. 5. They are not pregnant or breastfeeding. They do not have gallbladder inflammation or active gastrointestinal ulcers. 7. Patients do not have hemophilia or coagulation disease. Severe renal failure, ie GFR 30 ml / min or dialysis patients. 9- Signing informed written consent. 10. Not participating in other clinical trials at the same time. Exclusion criteria: Patients who are allergic to turmeric or curcumin supplement. Severe renal disease GFR 30 ml / min or dialysis patients. Patients who do not take more than a quarter of curcumin supplements during the study period. 4- Connecting the patient to the ventilator

Intervention groups
The patients in the control group will receive the national standard diet for the treatment of coronavirus with placebo. Patients in the curcumin group are treated with 160 mg of nanocurcumin for 14 days in addition to the standard regimen during hospitalization.

Main outcome variables
Clinical signs, Albumin concentration, CRP, ESR, Ferritin, Nutritional Risk Index (NRI), Interleukin-6

General information

Reason for update
Increase in secondary parameters that can be measured during the study

Acronym

IRCT registration information
IRCT registration number: **IRCT20211126053183N1**
Registration date: **2021-12-13, 1400/09/22**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-02, 1400/11/13**
Update count: **1**

Registration date
2021-12-13, 1400/09/22

Registrant information

Name
Sedigheh Ahmadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3634 5074

Email address
ahmadi.sedigheh@ymail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-11, 1400/09/20

Expected recruitment end date
2022-03-20, 1400/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of curcumin supplementaion on clinical symptoms , acute phase reactants and inflamatory cytokines in patients with covid-19 hospitalization

Public title
The effect of curcumin supplementaion on clinical symptoms , acute phase reactants and inflamatory cytokines in patients with covid-19 hospitalization
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
They have a positive PCR test or lung involvement in the imaging and 2- Hospitalized patients who are non-intubated. 3- They are over 18 years old .4- They have filled in the informed consent form5. 5-They are not pregnant or breastfeeding.6-They do not have gallbladder inflammation or active gastrointestinal ulcers.7. They do not have hemophilia or coagulation disease.8- renal failure with GFR <30 ml / min or dialysis patients.9- Signing informed written consent.10. Not participating in other clinical trials at the same time 11.cancer patients
Exclusion criteria:
1-Patients who are allergic to turmeric or curcumin.2-renal disease "GFR <30 ml / min" or dialysis patie.3-Patients who do not take more than a quarter of curcumin supplements during the study period.4-Connecting the patient to the ventilator
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
We will classify patients in group A or B using a simple randomization method using the random number table tool. Which group belongs to group A or group B is also done randomly. Randomization is done by a statistical consultant who is in the stage of implementing the research project without responsibility. The main researcher and the doctor and the patient have no role in the randomization process and completely without Are informed.
Blinding (investigator's opinion)
Double blinded
Blinding description
The prescribing physician and patients participating in the research project are unaware that they have received the drug or placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
amir 3,25/4 farhang shahr ,shahid rajaee Blvd ,shiraz
City
shiraz
Province
Fars
Postal code
71859-39688
Approval date
2021-10-17, 1400/07/25
Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1400.03

Health conditions studied

1

Description of health condition studied
covid-19
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Albumin, ferritin,CRP, ESR, interleukin 6,WBC,total lymphocyte count(TLC) Alanine Aminotransferase(ALT)(ALT),Aspartate Amino transferase(AST),LDH, resperatory oxygen saturation (SpO2) Nutritional Risk Index (NRI)
Timepoint
The first day of study, the fourteenth day of study
Method of measurement
Blood test, Nutritional Risk Index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: They receive 4 capsules of curcumin 40 mg daily made by Elixir Nano Drug Company for 14 days.
Category
Treatment - Other

2

Description
Control group: receive 4 placebo daily for 14 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi, Namazi and Ali Asghar Hospital in Shiraz
Full name of responsible person
sedigheh ahmadi
Street address
amir3,farhang shahr ,shahid rajaee blv,shiraz
City
shiraz
Province
Fars
Postal code
7185939688
Phone
+98 71 3634 5074
Email
ahmadi.sedigheh@ymail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
mahtab memarpour
Street address
shiraz university medical science
City
shiraz
Province
Fars
Postal code
71348-14336
Phone
+98 71 3235 7282
Email
vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
seyed jalil masoumi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
roshd center ,neshat Ave,shiraz
City
shiraz
Province
Fars
Postal code
7134874853
Phone
+98 71 3233 2313
Email
sjm@sums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
sedigheh ahmadi
Position
phd candidate
Latest degree
Master
Other areas of specialty/work

Nutrition

Street address

25/4,farhang shahr Ave,shiraz

City

shiraz

Province

Fars

Postal code

71859-39688

Phone

+98 71 3634 5074

Email

ahmadi.sdigheh@ymail.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

sedigheh ahmadi

Position

phd candidate

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

25/4,farhang shahr,shiraz

City

shiraz

Province

Fars

Postal code

71859-39688

Phone

+98 71 3634 5074

Email

ahmadi.sedigheh@ymail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

A report on which patients are in the medication or placebo group, as well as a report on test results and questionnaires will be available

When the data will become available and for how long

9 months after publication Results

To whom data/document is available

Our data will be accessible to those who are academic and scientific researchers

Under which criteria data/document could be used

The use of data for the development of other clinical trial studies or meta-analysis studies is unrestricted

From where data/document is obtainable

Send email to ahmadi.sedigheh@ymail.com or sjm@sums.ac.ir

What processes are involved for a request to access data/document

9 months after the publication of the article, an email will be sent to the listed address and the results will be sent within 2 month

Comments