

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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 above 18 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@gmail.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 rajaei 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

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Email

ahmadi.sedigheh@gmail.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

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71348-14336

Phone

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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

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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

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Position
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Other areas of specialty/work
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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.sdigheh@gmail.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