

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Effect of nanocurcumin supplementation on the severity of symptoms and length of hospital stay in patients with COVID-19

#### Protocol summary

##### Study aim

The aim of this study is to determine the effect of nanocurcumin supplementation on serum level of hs-CRP, the severity of symptoms and length of hospital stay in patients with COVID-19.

##### Design

The present study is a parallel randomized clinical trial with a control group.

##### Settings and conduct

Patients will be randomly divided to two groups of 24: intervention group (receiving nanocurcumin supplement) and control group (receiving placebo). Height, weight, and waist circumference will be measured and questionnaires for severity of infection symptoms of upper and lower respiratory tract will be filled out. Ten milliliter fasting blood will be taken from all patients at the beginning and end of the intervention.

##### Participants/Inclusion and exclusion criteria

Patients aged 30 to 70 years with confirmation of COVID-19 (having a positive PCR test or involved lung CT-scan) who do not require ICU admission will be included in the study. Patients with a history of chemotherapy, organ transplants, malignancies, dialysis, CABG, liver failure, HIV, heart attack and stroke in the past 3 months, uncontrolled diabetes, known food allergies, and people with BMI over 40 and pregnant and lactating women will not be included in the study.

##### Intervention groups

The intervention group will receive 4 capsules daily, each containing 40 mg of nanocurcumin, and the control group will receive 4 placebo capsules daily, which is completely similar to the nanocurcumin supplement, for 6 days.

##### Main outcome variables

hs-CRP, recovery percentage, percentage of oxygen saturation, severity of infection symptoms of upper and lower respiratory tract, CBC

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131125015536N13**

Registration date: **2020-10-03, 1399/07/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-10-03, 1399/07/12**

Update count: **0**

##### Registration date

2020-10-03, 1399/07/12

##### Registrant information

##### Name

Mohammad Javad Hosseinzadeh

##### Name of organization / entity

School of Nutritional Sciences and Dietetics, TUMS

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8899 3059

##### Email address

mhosseinzadeh@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-21, 1399/03/01

##### Expected recruitment end date

2020-12-20, 1399/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Effect of nanocurcumin supplementation on the severity of symptoms and length of hospital stay in patients with COVID-19

**Public title**

Assessment of the effect of nanocurcumin supplement in patients with COVID-19

**Purpose**

Supportive

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

Confirmation of Covid-19 by positive PCR test or lung scan Admission to hospital Corona wards other than ICU Filling out the informed consent form by the patient or the patient's first-degree relatives

**Exclusion criteria:**

Chemotherapy People living with HIV History of heart attack and stroke in the last 3 months History of CABG Dialysis patients Transplantation of body organs Pregnancy and lactation People with BMI above 40 Known food allergies Having any liver failure Malignancies Uncontrolled Diabetes (A1c>7.5)

**Age**

From **30 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done by permuted block method. First, all possible quadruple blocks are considered and a number is assigned to each of them. Then, using a table of random numbers and the number assigned to each block, a random sequence is determined. Eligible individuals included in the study are placed in the intervention or control group according to the sequence determined based on randomization.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In order to keeping patients, clinical caregivers, and the outcome assessor blind, the placebo will be prepared of the same color and shape as the supplement so that no one could distinguish the supplement from the placebo. The main researcher, who is not in direct contact with patients, is the only person who is not blind and pours supplements and placebos into exactly the same cans, specifies the cans with a three-digit number in no particular order and gives the cans to the outcome assessor, who is responsible for entering patients into the study and giving them the supplements. The randomization sequence will be kept by the main

researcher, and he/she will inform the outcome assessor that which can (based on the three-digit code) should be given to the next patient. In this way, the outcome assessor is not able to interfere with the order of patients' entering and will be completely blind to the contents of the can that should be given to the next patient.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics Committee on Research, Research and Technology Department of Tehran University of Medical Sci

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Floor 6, Central Organization of University, corner of Qods St., Keshavarz Blvd.

**City**

Tehran

**Province**

Tehran

**Postal code**

-

**Approval date**

2020-04-26, 1399/02/07

**Ethics committee reference number**

IR.TUMS.VCR.REC.1399.28

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

COVID-19

**ICD-10 code**

U07.1

**ICD-10 code description**

Coronavirus infection, unspecified

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

hs-CRP

**Timepoint**

Before and after 6 days of supplementation

**Method of measurement**

ELISA

## 2

### **Description**

Percentage of recovery

### **Timepoint**

Before and after 6 days of supplementation

### **Method of measurement**

CT scan of the lungs

## **Secondary outcomes**

### 1

### **Description**

Percentage of oxygen saturation

### **Timepoint**

Before the intervention and then daily until discharge

### **Method of measurement**

Pulse oximeter

### 2

### **Description**

Severity of infection symptoms of upper and lower respiratory tract

### **Timepoint**

Before the intervention and then daily during the supplementation period

### **Method of measurement**

Questionnaire

### 3

### **Description**

Complete Blood Count

### **Timepoint**

Before and after 6 days of supplementation

### **Method of measurement**

Automated cell count

## **Intervention groups**

### 1

### **Description**

Intervention group: People in the intervention group will receive nanocurcumin supplement at a dose of 160 mg per day for 6 days. Curcumin is a natural polyphenolic antioxidant responsible for the turmeric yellow color. Nanocurcumin supplements are produced in the form of 40 mg capsules by Exir Nano Sina Company, and patients will receive 4 supplements orally (every 12 hours 2 capsules) for 6 days in addition to the routine treatment,.

### **Category**

Rehabilitation

### 2

### **Description**

Control group: People in the control group are given placebo capsules that are completely similar to nanocurcumin supplements in terms of shape and color

and are asked to take 4 placebo capsules daily (every 12 hours 2 capsules) for 6 days.

### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shariati Hospital

##### **Full name of responsible person**

Neda Alijani

##### **Street address**

Shariati Hospital, Jalal Al-Ahmad Intersection, North Kargar St.

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1411713135

##### **Phone**

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##### **Fax**

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##### **Email**

shariatihosp@tums.ac.ir

##### **Web page address**

<http://shariati.tums.ac.ir/#>

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Ziaian Hospital

##### **Full name of responsible person**

Saied Reza Jamali Moghadam

##### **Street address**

Ziaian Medical Center, Abuzar Square, Qapan Crossroads, Qazvin St.

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##### **Postal code**

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##### **Phone**

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##### **Email**

ziaeian@tums.ac.ir

##### **Web page address**

<https://ziaeian.tums.ac.ir/>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Research and Technology Department of University

**Street address**

Floor 6, Central Organization of University, corner of Qods St., Keshavarz Blvd.

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-

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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**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Javad Hossein Zadeh

**Position**

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**

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**Full name of responsible person**

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**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Fatemeh Taheri

**Position**

Ph.D student

**Latest degree**

Master

**Other areas of specialty/work**

Biochemistry

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f.taheri6474@gmail.com

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available