

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### **Evaluation of the effect of nano micelles containing curcumin (Sina Ccurcumin) as a therapeutic supplement in patients with COVID-19 and investigating of immune responses balance changes following treatment: A randomized double blind clinical trial.**

#### **Protocol summary**

##### **Study aim**

Clinical study to investigate the effectiveness of curcumin-containing nanomaterials and its effects on immune cell balance as a therapeutic supplement in the treatment of COVID-19

##### **Design**

Clinical trial with control groups using placebo with parallel group, double-blind, randomized trials will be performed on 40 COVID-19 patients which will be randomized using encoded sealed wax boxes.

##### **Settings and conduct**

Patients are selected from the COVID-19 ward of Shahid Mohammadi Hospital in Bandar Abbas. Patients who enter the study receive standard treatment with nanocurcumin or placebo within two weeks. the study is blinded by the therapist, patient, data collector, and analyzer through randomly encoded boxes. on days 1, 7, and 14 of the study, clinical history and blood samples are taken from patients.

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria: Laboratory-approved COVID-19 tests  
Both gender Age between 18 and 75 years Signing a written consent Lack of participation in other clinical trials ;Exclusion criteria Pregnancy and lactation Allergy to turmeric or curcumin Smoking Patient connected to the ventilator SaO<sub>2</sub> less than 90% or PaO<sub>2</sub> less than 8 kPa Having comorbidities (such as severe renal failure Glomerular filtration rate less than 30 ml / min, liver failure ,Congestive heart failure, or Chronic obstructive pulmonary disease) History of gallstones History of gastritis or active gastrointestinal ulcer

##### **Intervention groups**

In addition to the usual treatments, in the intervention group, 40mg nanocurcumin capsules 4 mg per day (after breakfast, lunch and dinner, one before bedtime) for 2 weeks, and in the placebo group, capsules with the same

appearance are prescribed

##### **Main outcome variables**

Effectiveness of nano micelles containing curcumin as a complementary treatment in improving symptoms of patients with COVID-19 and examining changes in the immune cell balance

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20200611047735N1**

Registration date: **2020-06-19, 1399/03/30**

Registration timing: **prospective**

Last update: **2020-06-19, 1399/03/30**

Update count: **0**

##### **Registration date**

2020-06-19, 1399/03/30

##### **Registrant information**

##### **Name**

Amin Reza Nikpoor

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

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 76 3333 7192

##### **Email address**

nikpoora@hums.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2020-07-05, 1399/04/15  
**Expected recruitment end date**  
2020-09-05, 1399/06/15  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Evaluation of the effect of nano micelles containing curcumin (Sina Ccurcumin) as a therapeutic supplement in patients with COVID-19 and investigating of immune responses balance changes following treatment: A randomized double blind clinical trial.

**Public title**  
Evaluation of the effect of nano micelles containing curcumin (Sina Ccurcumin) as a therapeutic supplement in patients with COVID-19

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Laboratory-approved COVID-19 tests (2019-nCoV Real-Time RT-PCR) (preferably at a particular center or university-approved center) regardless of clinical manifestations and close contact history Signing a written consent form No simultaneous participation in other clinical trials  
**Exclusion criteria:**  
Pregnancy and lactation History of allergy to turmeric or curcumin products Smoking (more than 5 cigarettes a day) Patient connected to the ventilator Clinical evidence for respiratory failure at the time of hospitalization / admission ( $SaO_2 \leq 90\%$  or  $PaO_2 < 8$  kPa) Having comorbidities (such as severe renal failure Glomerular filtration rate less than 30 ml / min, liver failure ,Congestive heart failure, or Chronic obstructive pulmonary disease) History of gallstones History of gastritis or active gastrointestinal ulcer

**Age**  
From **18 years** old to **75 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The randomization method in this study is used as an individual randomization using a sealed sealed envelope

randomization tool. In this case, the third person was responsible for picking up and selecting the envelopes as a random arrangement in which the placebo and the main drug were randomly divided among the patients. The study person and the analyst will not be aware of how the randomization happened.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In order to perform the blinding, according to the number of patients, the nanocurcumin and placebo, which are quite similar in shape and characteristics, is randomly placed in the same boxes and the boxes are coded. The codes related to the drug and placebo will be provided by a third party, and the therapist, patient, data collector, and analyzer will not be notified, and the boxes will be given to patients upon arrival. .

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Hormozgan University of Medical Sciences

**Street address**

Imam Hussain Blvd, School of Medicine, Immunology Department

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7916613885

**Approval date**

2020-06-10, 1399/03/21

**Ethics committee reference number**

IR.HUMS.REC.1399.174

**Health conditions studied**

1

**Description of health condition studied**

COVID-19

**ICD-10 code**

• U07.1

**ICD-10 code description**

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Clinical symptoms

#### Timepoint

On a weekly basis, patients are examined clinically on days 1, 7, and 14

#### Method of measurement

Clinical examinations

### 2

#### Description

Immune cell balance

#### Timepoint

On a weekly basis, blood samples are taken from patients and patients are examined on days 1, 7 and 14.

#### Method of measurement

Molecular experiments

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients with COVID-19, in addition to routine drug treatment, will receive 40 mg of nano curcumin capsules 4 times a day (one for breakfast, one for lunch, one for dinner and one before bedtime) for 2 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: COVID-19 patients will receive 4 placebo a day (after breakfast, lunch and dinner one and one before bedtime) for 2 weeks in addition to routine medication.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Mohammadi hospital

##### Full name of responsible person

Amin Reza Nikpoor

##### Street address

Jomhuri eslami Blvd

##### City

Bandar Abbas

#### Province

Hormozgan

#### Postal code

7919915519

#### Phone

+98 76 3333 7192

#### Email

nikpoora@hums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bandare-abbas University of Medical Sciences

##### Full name of responsible person

teymour agha mollaie

##### Street address

Jomhuri esmami Blvd

##### City

Bandar Abbas

##### Province

Hormozgan

##### Postal code

7919915519

##### Phone

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##### Email

nikpoora@hums.ac.ir

#### Grant name

990126

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

##### Full name of responsible person

Amin Reza Nikpoo

##### Position

Assistant professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Immunology  
**Street address**  
Immunology Department, School of Medicine, Imam-  
Hussein Blvd  
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7919693116  
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+98 76 3371 0370  
**Email**  
nikpoora@hums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Bandare-abbas University of Medical Sciences  
**Full name of responsible person**  
Amin Reza Nikpoor  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Immunology  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Bandare-abbas University of Medical Sciences  
**Full name of responsible person**  
Amin Reza Nikpoor  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.

## Other areas of specialty/work

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nikpoora@hums.ac.ir

## 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

Yes - There is a plan to make this available

### Title and more details about the data/document

After extraction, the data will be analyzed for presentation as a scientific paper and report.

### When the data will become available and for how long

After the study, it is possible to access

### To whom data/document is available

There are no restrictions on access.

### Under which criteria data/document could be used

The rights to use the project are reserved. If there is a request to access the data, it will be done with the opinion of the correspondence of the present project and the type of use of the data will be according to the opinion of the correspondence of the present project.

### From where data/document is obtainable

Correspondence with correspondence of the present project.

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

In order to access the data, it will be decided by correspondence of the present project.

### Comments