# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 SaO2 less than 90% or PaO2 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)

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**Email address**
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**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 (SaO2 ≤ 90% or PaO2 <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
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Jomhouri eslami Blvd
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Bandare-abbas University of Medical Sciences
**Full name of responsible person**
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**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**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
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**