

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Evaluation the Efficacy of CURCUDEN in Patients with COVID-19 Pneumonia

#### Protocol summary

##### Study aim

Evaluating the effectiveness of CURCUDEN products as adjunctive therapy in the treatment of pneumonia in patients with COVID-19

##### Design

A phase 3 randomized clinical trial with control and intervention groups, double blinded, 20 patients, allocated concealment by the central randomization method.

##### Settings and conduct

Intervention group receives 2 capsules of CURCUDEN® every 12h with the recommended treatment regimen for COVID-19 according to the national protocol. From the day of entrance, the Sepsis-related Organ Failure Assessment standard for calculating respiratory, cardiovascular, neurological, renal, coagulation and hepatic function is calculated and its average is reported. Also, the criterion for classification of 7 (category-ordinal scale), complete counting and differentiation of blood cells (CBC diff, acute phase C protein, erythrocyte sedimentation rate and prothrombin time, lactate dehydrogenase, creatine phosphokinase, ferritin, creatinine, and the National Early Warning Criteria 2 were measured on days 1, 5, and fourteen of treatment, compared with control group. Measurements of interleukin 6 levels, RT-PCR virus testing, and CT scans of the lungs are also performed on days one and five of treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Virological diagnosis of SARS-CoV-2 infection by RT-PCR Positive imaging findings: Condensation, Grand Glass turbidity or bilateral pulmonary infiltration on CT scan or Chest X-ray Need to get extra oxygen to maintain  $SO_2 > 94\%$  or  $PaO_2 / FiO_2 > 300$  Exclusion criteria : less than 18 years Septic shock Pregnancy and lactation Intubated and under mechanical ventilation Allergic to curcumin Admitted to the ICU

##### Intervention groups

Every 12h, Intervention group received 2 CURCUDEN

capsules & Control group, takes 2 placebos in addition to the main treatment protocol

##### Main outcome variables

SOFA; RT-PCR; CPK; CRP; Ferritin; IL-6

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170128032241N3**

Registration date: **2020-08-17, 1399/05/27**

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

Last update: **2020-08-17, 1399/05/27**

Update count: **0**

##### Registration date

2020-08-17, 1399/05/27

##### Registrant information

##### Name

Maryam Mohajeri

##### Name of organization / entity

Alborz Nanomed Tech Co.

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6691 9151

##### Email address

info@nanomed.ws

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-21, 1399/03/01

##### Expected recruitment end date

2020-09-21, 1399/06/31

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation the Efficacy of CURCUDEN in Patients with COVID-19 Pneumonia

**Public title**  
Evaluation the Efficacy of CURCUDEN 35 in Patients with COVID-19

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Virological diagnosis of SARS-CoV-2 infection by RT-PCR  
Positive imaging findings: Condensation, Grand Glass opacity or bilateral pulmonary infiltration on CT scan or Chest X-ray  
Need to get extra oxygen to maintain  $SO_2 > 94\%$  or  $PaO_2 / FiO_2 > 300$

**Exclusion criteria:**  
Age less than 18 years  
The patient has septic shock  
Pregnancy and lactation  
The patient is intubated and under mechanical ventilation  
The patient was admitted to the ICU  
Having an allergy to curcumin

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Data analyser

**Sample size**  
Target sample size: **20**

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

**Randomization description**  
Using the table of random numbers, we assign patients codes in the specified range, then categorize the individual codes into the intervention group and the pair codes into the control group. The central randomizing method is used for allocation concealment. For this purpose, even and odd codes are provided to the researcher conducting the project, and sampling is performed in the medical center of Taleghani Hospital. Based on the order in which the participants entered the study, the researcher randomly assigned the participant to one of the two groups of treatment and control (even and odd codes). At the end of the study, and after the intervention, unblinding will be done with the Post-study unblinding model to prevent any bias in the study.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
We mark drug with code A and placebo with the code B,

only the analyst is aware of this codes, each group of patients receive A or B randomly, the physician and the patient are not aware of this codes.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti Medical University

##### Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733141

#### Approval date

2020-05-10, 1399/02/21

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1399.085

## Health conditions studied

### 1

#### Description of health condition studied

covid-19 pneumonia Disease

#### ICD-10 code

U07.1

#### ICD-10 code description

covid-19 pneumonia

## Primary outcomes

### 1

#### Description

1- Evaluation of clinical variables involved in patients' recovery including mechanical ventilation

#### Timepoint

On days 1, 5 and 14 of the start of treatment

#### Method of measurement

Spirometry test

### 2

#### Description

2- Organ failure and comparison of these results in the

two groups of treatment and control

**Timepoint**

On days 1, 5 and 14 of the start of treatment

**Method of measurement**

Examination and registration of clinical signs

**3**

**Description**

3- Mortality and comparison of these results in the two groups of treatment and control

**Timepoint**

On days 1, 5 and 14 of the start of treatment

**Method of measurement**

Record vital signs

**4**

**Description**

4- The length of hospital stay and comparison of these results in the treatment and control groups

**Timepoint**

On days 1, 5 and 14 of the start of treatment

**Method of measurement**

Evaluation of the length of hospital stay

**5**

**Description**

5- Length of ICU hospitalization and comparison of these results in the treatment and control groups

**Timepoint**

On days 1 and 5 of the start of treatment

**Method of measurement**

Check the period of hospitalization in the ICU

**6**

**Description**

6- Receiving oxygen and comparing these results in the treatment and control groups

**Timepoint**

On days 1, 5 and 14 of the start of treatment

**Method of measurement**

Nursing information on the use of oxygen capsules

**7**

**Description**

7- The length of the negative period of PCR test and comparison of these results in the treatment and control groups

**Timepoint**

On days 1 and 14 of the start of treatment

**Method of measurement**

Polymerase Chain Reaction

**8**

**Description**

8- Comparison of interleukin-6 levels in the treatment and control groups

**Timepoint**

On days 1 and 14 of the start of treatment

**Method of measurement**

Polymerase Chain Reaction

**9**

**Description**

9- Comparison of patients' ferritin levels in treatment and control groups

**Timepoint**

On days 1, 5 and 14 of the start of treatment

**Method of measurement**

Blood biochemical test

**10**

**Description**

10- Comparison of patients' CRP levels in treatment and control groups

**Timepoint**

On days 1, 5 and 14 of the start of treatment

**Method of measurement**

Blood biochemical test

**11**

**Description**

11- Length of improvement period of patients' lung imaging results and comparison of results in treatment and control groups

**Timepoint**

On days 1 and 5 of the start of treatment

**Method of measurement**

lung CT Scan

**12**

**Description**

12- Lymphocyte count and comparison of results in treatment and control groups

**Timepoint**

On days 1, 5 and 14 of the start of treatment

**Method of measurement**

Blood biochemical test

**13**

**Description**

13- Length of respiratory symptoms and comparison of results between treatment and control groups

**Timepoint**

On days 1, 5 and 14 of the start of treatment

**Method of measurement**

Check spirometric test information

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: Patients with covid-19 who use curcumin in addition to first-line drugs during treatment. Intervention group receive two capsules of CURCUDEN® every 12 hours in addition to the main treatment based on national guidelines for the treatment of hospitalized patients with COVID-19. Curcuden 35 is a drug used by Alborz Nanomed tech Company.

### Category

Treatment - Drugs

## 2

### Description

Control group: Patients with covid-19 who use placebo in addition to first-line drugs during treatment. Control group receive two capsules of placebo every 12 hours in addition to the main treatment based on national guidelines for the treatment of hospitalized patients with COVID-19.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani Hospital

##### Full name of responsible person

ماریا توکلی اردکانی

##### Street address

CHAMRAN HIWAY, YAMAN ST., SHAID ARABI ST.  
TALEGHANI Hospital

##### City

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##### Province

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1985711151

##### Phone

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##### Email

taleghani@sbmu.ac.ir

##### Web page address

<http://taleghani.sbmu.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Maria Tavakoli Ardakani

##### Street address

chamran Hiway, Yaman St. Arabi St.

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info@sbmu.ac.ir

##### Web page address

##### Grant name

##### Grant code / Reference number

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

No

##### Title of funding source

Mobtaker Electric Company ( METEC )

##### Proportion provided by this source

50

##### Public or private sector

Private

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

Industry

### 2

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Maryam Mohajeri

##### Street address

chamran Hiway, Yaman St. Arabi St.

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 23871

##### Email

info@sbmu.ac.ir

##### Grant name

##### Grant code / Reference number

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

No

##### Title of funding source

Alborz Nanomed-Tech Company

##### Proportion provided by this source

50

##### Public or private sector

Private

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

*empty*

**Country of origin**  
**Type of organization providing the funding**  
Industry

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Alborz Nanomed Tech. Co.  
**Full name of responsible person**  
Mehran Azodi  
**Position**  
Consultant  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Industrial Engineering- System Management  
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<http://www.nanomed.ws>

## Person responsible for scientific inquiries

### Contact

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Alborz Nanomed Tech Co.  
**Full name of responsible person**  
Maryam Mohajeri  
**Position**  
CEO, R&D manager  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Molecular Genetics, Nanomedicine  
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## Person responsible for updating data

### Contact

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Alborz Nanomed Tech Co.  
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## 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

No - There is not 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

No - There is not a plan to make this available

### Data Dictionary

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