# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 Assesment 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 SO2> 94% or PaO2 / FiO2> 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)
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**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 SO2> 94% or PaO2 / FiO2> 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.

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**Province**

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**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 controlgroups

**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 controlgroups

**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 thetreatment 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 intreatment 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 controlgroups

**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
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
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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**
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**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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## 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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**Position**

IT expert

**Latest degree**

Bachelor

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Information Technology

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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