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 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.

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 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
Maria Tavakoli Ardakani
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chamran Hiway, Yaman St. Arabi St.
City
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Postal code
1985717443
Phone
+98 21 23871
Email
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.
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Province
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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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Person responsible for scientific inquiries

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Name of organization / entity

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.

Full name of responsible person

Narges Shakeri

Position

IT expert

Latest degree

Bachelor

Other areas of specialty/work

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