# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Jun 2026

## Evaluation of the effect of cinnora supplement therapy in patients with severe form of COVID-19

### Protocol summary

**Study aim**
The effect of cinnora supplement therapy in patients with severe form of COVID-19

**Design**
Clinical trial with control group, parallel, and randomized groups on 80 patients. Random number table was used for randomization.

**Settings and conduct**
Study place: Shahid Beheshti Hospital, Kashan. Methods: Patients are randomly divided into two groups (case-control) according to a random number table. The study is a one-way blind study. The clinical caregiver dose not know how to assign patients to the two groups.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Patients with definitive diagnosis of COVID-19, and patients over 18 years. Exclusion criteria: Patient underwent tumor necrosis factor alpha inhibitors due to previous inflammatory disease, positive purified protein derivative test and active bacterial infection

**Intervention groups**
Patients in both groups receive standard treatment (corticosteroids and remdesivir and ceftriaxone antibiotics and oxygen therapy). Then one group receives cinnora medicine and one group does not. Patients treated with cinnora ampoules receive a dose of 80 mg subcutaneously. If needed, they will receive another 40 mg of cinnora after one week. Before receiving this drug, a purified protein derivative skin test should be performed and a chest x-ray should not indicate infection. In patients of both groups, clinical symptom such as oxygen saturation is recorded daily and laboratory criteria including C reactive protein will be measured daily for up to two weeks.

**Main outcome variables**
Arterial oxygen saturation

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20180209038673N6**
Registration date: **2022-04-26, 1401/02/06**
Registration timing: **retrospective**

Last update: **2022-04-26, 1401/02/06**
Update count: **0**

**Registration date**
2022-04-26, 1401/02/06

**Registrant information**

**Name**
Robab Sheikhpour

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-01-10, 1400/10/20

**Expected recruitment end date**
2022-03-11, 1400/12/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluation of the effect of cinnora supplement therapy in patients with severe form of COVID-19

**Public title**
The effect of cinnora supplement therapy in patients with severe form of COVID-19
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients over 18 years Patients with definitive diagnosis of COVID-19
**Exclusion criteria:**
Patients who treated with tumour necrosis factor α inhibitors due to previous inflammatory diseases. Positive purified protein derivative skin test. Active bacterial infection.
**Age**
From **18 years** old
**Gender**
Female

**Phase**
3
**Groups that have been masked**

- Care provider

**Sample size**
Target sample size: **80**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The randomization of the intervention and control groups is done based on quadruple blocks in Excel software. In this software, the intervention and control groups are placed alternately. In the next column, there are quadruple blocks. At the end, the random digits created by the software RND0 function are placed. We then arrange the numbers based on block columns and random values.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
In this study, clinical caregiver will not aware about prescription drugs.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethical Committee of Kashan University of Medical Sciences
**Street address**
Kashan University of Medical Sciences, Shahrdari Street, Kashan
**City**
Kashan
**Province**
Isfehan
**Postal code**
8715973474
**Approval date**
2021-12-06, 1400/09/15
**Ethics committee reference number**
IR. KAUMS. REC.1400.049

## Health conditions studied

**1**

**Description of health condition studied**
COVID-19 disease
**ICD-10 code**
B34.2
**ICD-10 code description**
Coronavirus infection, unspecified

## Primary outcomes

**1**

**Description**
Improvement of clinical symptoms (arterial oxygen)
**Timepoint**
Daily evaluation of clinical signs for up to two weeks
**Method of measurement**
Pulse oximeter

## Secondary outcomes

**1**

**Description**
C-reactive protein (CRP)
**Timepoint**
Daily evaluation of clinical signs for up to two weeks
**Method of measurement**
CRP kit

## Intervention groups

**1**

**Description**
Intervention group: Patients in the intervention group receive standard treatment, including corticosteroids (Abidi Company), 200 mg remdisiver (Ronak Company). Then, they receive 100 mg remdesivir for 5 days and 1 gr ceftriaxone antibiotics (Dana Company), and oxygen therapy. Then, patients receive 80 mg cinnora ampule, subcutaneously (CinnaGen Company). If needed, they will receive 40 mg of cinnora after one week.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Patients in the intervention group receive standard treatment, including corticosteroids (Abidi Company), 200 mg remdisiver (Ronak Company). Then, they receive 100 mg remdesivir for 5 days and 1 gr ceftriaxone antibiotics (Dana Company), and oxygen therapy.

**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Shahid Beheshti Hospital

**Full name of responsible person**
Khadijeh Ghavam Nezhad

**Street address**
Shahid Beheshti Hospital,Qotb-e Ravandi Blvd, Kashan

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Kashan University of Medical Sciences

**Full name of responsible person**
Hamid Reza Gilassi

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Kashan University of Medical Sciences, Shahrdari Street, Kashan

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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**
Kashan 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**
Kashan University of Medical Sciences

**Full name of responsible person**
Khadijeh Ghavam Nezhad

**Position**
Resident

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Infectious diseases

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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)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
No agreement has been reached between the members yet
**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**
Undecided - It is not yet known if there will be 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**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available