Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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+98 35 3623 5958

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r.sheikhpour@yahoo.com

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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CRL.Kaums@gmail.com

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 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