

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Cyclosporin for the Prevention and Treatment of COVID-19 Disease

Protocol summary

Study aim

Reducing in mortality and improve oxygenation in covid-19 patient's

Design

covid-19 patients admitted to the intensive care unit and who had severe respiratory failure and lack of adequate response to treatment were included in the group, and a 5 mg/kg cyclosporine ampoule was gradually infused. The general symptoms of patients and CT scans of patients were noted.

Settings and conduct

Patients admitted to the ICU who have respiratory failure and have not responded to treatment. They are selected and infused with cyclosporine ampoule patients and patients' symptoms are noted.

Participants/Inclusion and exclusion criteria

patient's admitted in ICU and wards

Intervention groups

covid-19 patients admitted to the intensive care unit and who had severe respiratory failure

Main outcome variables

improve oxygenation improve ct scans

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150107020592N22**

Registration date: **2020-05-25, 1399/03/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-25, 1399/03/05**

Update count: **0**

Registration date

2020-05-25, 1399/03/05

Registrant information

Name

Seyed Mohammad Reza Hashemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 9944

Email address

iran.criticalcare@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cyclosporin for the Prevention and Treatment of COVID-19 Disease

Public title

Cyclosporin for the Prevention and Treatment of COVID-19 Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

covid patients non-intubated patients Age between 18-80

Exclusion criteria:

Allergy to cyclosporin intubated patients

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Masih Daneshvari Hospital the Edjucational , Research and Treatment center

Street address

End of Niavaran, Darabadational , Research and Treatment center.

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2020-04-07, 1399/01/19

Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.058

Health conditions studied**1****Description of health condition studied**

covid-19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes**1****Description**

improve oxygenation

Timepoint

0,1,2,3,7after treatment with cyclosporin

Method of measurement

pulse oximeter

2**Description**

improve ct scan

Timepoint

seven day after cyclosporine treatment

Method of measurement

CT scan unit

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: patient under cyclosporin treatment: Patients who have acute respiratory failure due to covid-19 and do not respond to antiretroviral therapy due to the unknown nature of the disease to reduce inflammatory cytokines in patients with slow cyclosporine injections within two hours of infusion and seven days continue and the general condition of patients and symptoms Patient and CT-scans are checked

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Masih Daneshvari Hospital the Edjucational , Research and Treatment center

Full name of responsible person

Dr Seyyed Mohamadreza Hashemian

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran

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Email

iran.criticalcare@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Seyyed Mohamadreza Hashemian

Street address

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Mohammad Reza Hashemian

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Masih Daneshvari Hospital, Darabad, Niavaran Street, Tehran, Iran

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Seyed Mohammad Reza Hashemian

Position

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All patient information can be published after deleting the name

When the data will become available and for how long

It will take a month from the time of application

To whom data/document is available

All professors of medical universities in the country

Under which criteria data/document could be used

Help advance science

From where data/document is obtainable

professor hashemian in masih daneshvari hospital

What processes are involved for a request to access data/document

one month

Comments