

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluating the Efficacy of Ivermectin in the Treatment of COVID-19 Patients

Protocol summary

Study aim

Evaluating the efficacy of ivermectin in the treatment of COVID-19 patients

Design

Randomized open label clinical trial, with two arms with 1: 1 allocation ratio

Settings and conduct

This study will perform on patients with severe COVID-19 patients admitted to Labbafinejad Hospital in 1401. Patients are divided into groups A and B and receive medication according to the protocol. Vital signs and laboratory tests of the patients will evaluate by medical team on the first visit. The medical team will then evaluate vital signs, laboratory tests, and overall outcomes by the fifth day of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: Laboratory confirmation of COVID-19 virus by RT-PCR or imaging findings consistent with COVID-19, Severe disease (respiratory rate more than 30 per minute, oxygen saturation less than 94%, or pulmonary infiltration more than 50% in both lungs), Age above 18 years, Willingness to participate in this study. This study has no exclusion criteria.

Intervention groups

Group A, in addition to standard treatment, receives oral ivermectin 200 micrograms per kilogram of body weight for the first and third days of treatment. Group B, in addition to standard treatment, receive oral ivermectin at the same dose for the first, third, and fifth days of treatment.

Main outcome variables

Mortality and intubation requirement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210901052358N4**

Registration date: **2022-04-13, 1401/01/24**

Registration timing: **prospective**

Last update: **2022-04-13, 1401/01/24**

Update count: **0**

Registration date

2022-04-13, 1401/01/24

Registrant information

Name

Amirreza Keyvanfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4483 1899

Email address

amirrezakeyvanfar@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Efficacy of Ivermectin in the Treatment of COVID-19 Patients

Public title

Efficacy of Ivermectin in the treatment of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Laboratory confirmation of COVID-19 virus by RT-PCR or imaging findings consistent with COVID-19 Severe disease (respiratory rate more than 30 per minute, oxygen saturation less than 94%, or pulmonary infiltration more than 50% in both lungs) Age above 18 years Willingness to participate in this study

Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is a simple randomization that is done in the form of individual random units. The tool used to do this is a random numbers table. The method of constructing a random sequence is that first the researcher selects one of the numbers with his eyes closed and then moves in the right direction. Odd numbers are considered for intervention and even numbers are for control. Random concealment is also performed using sequentially numbered sealed opaque envelopes (SNOSE).

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Organizational Committee of Ethics in Biomedical Research, Shahid Beheshti University of Medical Sci

Street address

Shahid Beheshti University of medical sciences, Arabi St., Daneshjoo Blvd., Yaman St., Chamran highway.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-11-22, 1399/09/02

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.701

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Mortality

Timepoint

5th day of hospitalization

Method of measurement

Patient medical record

2

Description

Intubation requirement

Timepoint

5th day of hospitalization

Method of measurement

Patient medical record

Secondary outcomes

1

Description

Oxygen saturation

Timepoint

First and fifth days of hospitalization

Method of measurement

Pulse oximeter

2

Description

Respiratory rate

Timepoint

First and fifth days of hospitalization

Method of measurement

Physical examination by physician

3

Description

Serum CRP level

Timepoint

First and fifth days of hospitalization

Method of measurement

Laboratory report

4

Description

Lymphocyte count

Timepoint

First and fifth days of hospitalization

Method of measurement

Laboratory report

Intervention groups

1

Description

Intervention group: Group A, in addition to standard treatment, receives oral ivermectin 200 micrograms per kilogram of body weight for the first and third days of treatment. Standard treatments include serum therapy, vitamins, supplemental oxygen, and remdesivir (200 mg intravenously for first day and 100 mg daily intravenously for the next 4 days).

Category

Treatment - Drugs

2

Description

Intervention group: Group B, in addition to standard treatment, receives oral ivermectin 200 micrograms per kilogram of body weight for the first, third, and fifth days of treatment. Standard treatments include serum therapy, vitamins, supplemental oxygen, and remdesivir (200 mg intravenously for first day and 100 mg daily intravenously for the next 4 days).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Labbafinejad hospital

Full name of responsible person

Amirreza Keyvanfar

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9th Boostan St., Pasdaran, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, No. 2, Arabi St., Yemen St., Chamran Highway, Tehran, Iran

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1983969411

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+98 21 2243 9780

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Mpajouhesh@sbmu.ac.ir

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

Amirreza Keyvanfar

Position

Research assistant

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Amirreza Keyvanfar

Position

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Latest degree

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Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amirreza Keyvanfar

Position

Research assistant

Latest degree

Medical doctor

Other areas of specialty/work

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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

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