

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of the effect of Ivermectin in hospitalized patients with COVID-19 in Imam Reza Hospital in Mashhad

Protocol summary

Study aim

Determining the effect of Ivermectin administration on one-month death of patients with Covid-19

Design

Clinical trial has a control group with parallel groups, this study was open label due to the lack of placebo, so there is no point in being blind.

Settings and conduct

Among patients referred to Imam Reza hospital, 80 patients were selected for study whose diagnosis is confirmed by inclusion criteria. These patients were randomly divided into two groups with equal numbers. In control group, patients receive all available treatments for Covid-19 according to the latest treatment protocol, and in case group, in addition to similar treatments in the control group, patients are prescribed Ivermectin with dose: 200 microgram per kilogram, in one dose up to two days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Covid-19 whose diagnosis is confirmed by: Physicians clinical diagnosis with patients clinical symptoms. O₂ saturation less than 93% laboratory parameters (ESR, CRP, FERRITIN, CBC and lymphocyte count, D-dimer) Positive Real time PCR test for SARS-CoV-19 Age between 16-75 Exclusion criteria: Pregnancy and breast feeding Concomitant use of Warfarin over 75 years

Intervention groups

In addition to similar treatments in the control group, patients are prescribed Ivermectin with dose 200 microgram per kilogram, up to two days in a row. In control group, patients receive all available treatments for Covid-19 according to the latest protocol.

Main outcome variables

hospital stay, severity of disease is measured by physician, improvement of laboratory parameters (ESR, CRP, FERRITIN, CBC and lymphocyte count, D-dimer), improvement of O₂ saturation, need for mechanical ventilation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190602043787N3**

Registration date: **2020-07-20, 1399/04/30**

Registration timing: **prospective**

Last update: **2020-07-20, 1399/04/30**

Update count: **0**

Registration date

2020-07-20, 1399/04/30

Registrant information

Name

Zahra Ataee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3854 3031

Email address

ataeez@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Ivermectin in hospitalized patients with COVID-19 in Imam Reza Hospital in Mashhad

Public title

Ivermectin effect in the treatment of patients with covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Covid-19 patients whose diagnosis is confirmed by clinical signs of patients and other laboratory parameters, are checked: physicians clinical diagnosis includes the patients general condition and clinical symptoms. O2 saturation less than 93% in infected patients laboratory parameters (ESR, CRP, Ferritin, CBC, Lymph count, D-dimer (if present)) Positive Real time PCR test result for Covid-19 Patients in the age range of 16-75 years

Exclusion criteria:

Pregnancy and breastfeeding Concomitant use of warfarin Patients over 75 years old

Age

From **16 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be considered by simple randomization through random number table that produced from www.randomization.com. Patients are randomly assigned to the drug receiving group (case) or the control group without receiving the placebo.

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Quraish bilding of MUMS, Daneshgah St, Mashhad, Iran Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2020-06-22, 1399/04/02

Ethics committee reference number

IR.MUMS.REC.1399.307

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.02

ICD-10 code description

COVID-19 disease

Primary outcomes

1

Description

Duration of hospital stay

Timepoint

Death rate up to 30 days from the time of entry into the trial

Method of measurement

Review files

2

Description

Illness severity

Timepoint

Daily

Method of measurement

By the physician clinical diagnosis criteria include the patients general condition and clinical symptoms and improvement of laboratory parameters (ESR, CRP, Ferritin, CBC, Lymph count, D-dimer (if available)) and improvement O2 saturation

Secondary outcomes

1

Description

Need to mechanical ventilation

Timepoint

Daily

Method of measurement

The patients general condition and clinical symptoms and O2 saturation

Intervention groups

1

Description

Intervention group:in addition to similar treatments of control group,patients uses the following dose of Ivermectin 3 miligram manufactured by Erophartech/France : 200 microgram per kilogram that in a normal weight about 50-65 kilogram is about 12 miligram is equivalent to 4 tablets in one dose, in 65-80 kilogram is about 15 miligram is equivalent to 5 tablets in one dose and in weighing more than 80 kilogram with 200 microgram per kilogram in one dose daily up to two days.

Category

Treatment - Drugs

2

Description

Control group: Patients will be treated with antiviral drugs according to existing standards with the same dose and frequency of administration as the standard treatment regimen (for example hydroxychlorquin 200 mg , 2 tablets every 12 hours for first day and 1 tablet every 12 hours for 7 days)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Zahra Atae

Street address

Emam Reza hospital, Emam Reza Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Saman Soleimanpour

Position

MD, Ph.D, assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Microbiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Atae

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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Position

assistant professor

Latest degree

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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