# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Oct 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 acontrol 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 Emam 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,FERRITTIN,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,FERRITTIN,CBC and lymphocyte count ,D-dimer ) , improvement of O2 saturation, need for mecanical 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,Ferrittin,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**
Ethic's committee of Mashhad University of Medical Sciences
**Street address**
Quraish bilding of MUMS,Daneshghah 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 ctiteria includ the patients general condition and clinical symptoms and improvement of laboratory parameters(ESR,CRP,Ferrittin,CBC,Lymph count,D-dimer(if available)) and improvement O2 saturation

## Secondary outcomes

### 1

**Description**
Need to mecanical 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 Ataee

**Street address**
Emam Reza hospital, Emam Reza Ave

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ataeez@mums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

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

**Full name of responsible person**
Dr Mohsen Tafaghodi

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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**

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**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**
Internal Medicine

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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