

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Dec 2022

### 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. O<sub>2</sub> 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 O<sub>2</sub> 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](http://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

##### City

Mashhad

##### Province

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##### Postal code

9137913316

##### Phone

+98 51 3854 3031

##### Email

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

##### Street address

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

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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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Emam Reza hospital, Emam Reza Ave

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Soleimanpours@mums.ac.ir

## 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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**Email**

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**Person responsible for updating data**

**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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**Email**

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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