

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### To study the effect of Metronidazole and Ivermectin in the recovery of the infected patients with COVID-19 compared with protocol treatment: triple-blind randomized clinical trial

#### Protocol summary

##### Study aim

To determine the effect of Metronidazole on the recovery of patients infected with COVID-19 To determine the effect of Ivermectin on the recovery of patients infected with COVID-19 To compare the effect of Ivermectin and Metronidazole in the recovery of patients infected with COVID-19

##### Design

Triple blind parallel group randomized trial, phase 3 on 135 patients, with control group using random number table method of sampling

##### Settings and conduct

The study will be done in confirmed Cov-19 patients admitted to Shiraz teaching hospitals. Both the main drugs, ivermectin and metronidazole, and the control group's drug will be labeled as A, B, and C, and will be unknown to the patients, therapist and data analyzer.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalized patient 18 years and older with positive Covid-19 test (infection would be confirmed by RT-PCR or CT-scan), willing to participate in the study. Exclusion criteria: History of allergy to Ivermectin and/or Metronidazole, Pregnant mothers, COPD patients, Patients with suspected ILD, Patients with a long history of diabetes mellitus, Cirrhotic patients, Epileptic patients, Patients with severe renal insufficiency (GFR below 20), do not participate in another RCT.

##### Intervention groups

Interventions are defined by daily intake of 0.2 mg/kg body weight Ivermectin orally (3 mg tablets) as a single dose. In the second intervention group, 8 mg/kg body weight of Metronidazole up to a maximum of 500 mg every 12 hours for 7 days. The control group will receive only protocol-based treatment. Medication does not interfere with meals.

##### Main outcome variables

The time to eliminate shortness of breath, need for

oxygen, reduction of CRP, normalization of lymphopenia , hospital stay, the likelihood of hospitalization in the ICU and the likelihood of mortality will be assessed.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180612040068N1**

Registration date: **2021-04-19, 1400/01/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-04-19, 1400/01/30**

Update count: **0**

##### Registration date

2021-04-19, 1400/01/30

##### Registrant information

##### Name

Mohammadreza Heydari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3738 6272

##### Email address

heydari280@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-05, 1399/12/15

##### Expected recruitment end date

2021-04-21, 1400/02/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

To study the effect of Metronidazole and Ivermectin in the recovery of the infected patients with COVID-19 compared with protocol treatment: triple-blind randomized clinical trial

**Public title**

To study the effect of Metronidazole and Ivermectin in hospitalized patients with COVID-19.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Hospitalized patient with positive corona test

**Exclusion criteria:**

Allergic history to Metronidazole or Ivermectin or hypersensitivity reaction to them during trial. pregnant patients COPD Patients suspected to ILD long history of diabetes cirrhotic patients Epileptic patients patients with sever renal failure ang GFR below 20 participating in another RCT

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**

Target sample size: **135**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Permuted block random allocation Three therapies and six houses blocks In each step when a new block is selected, we select one of the 6 blocks by rolling the dice

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Both Ivermectin and Metronidazole, and the control group's drug are labeled as A, B and C, and are unknown to the patient and therapist (Allocation Concealment). Prescription of the medicine to the patients in each group will be ordered by a third person, preferably an epidemiologist.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Zand Blvd., Shiraz University of Medical Sciences

**City**

Shiraz

**Province**

Fars

**Postal code**

71348-14336

**Approval date**

2020-06-20, 1399/03/31

**Ethics committee reference number**

IR.SUMS.REC.1399.446

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

Coronavirus infection

**ICD-10 code**

B34.2

**ICD-10 code description**

Coronavirus infection, unspecified

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

The main consequences of this trial including; the time of disappearance of shortness of breath, the need for oxygen, the reduction of CRP, the normalization of lymphopenia that will be measured by specialists. Also, the effectiveness of each treatment method will be measured based on the length of hospital stay, the likelihood of hospitalization in the ICU, and the likelihood of mortality.

**Timepoint**

Before starting treatment and at the time of discharge, which should not be less than 5 days

**Method of measurement**

Blood factors with laboratory methods. Temperature with digital thermometer. Blood pressure with mercury sphygmomanometer or digital pulse oximeter. Other cases with direct observation

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

The first intervention group is the patients that will intake 0.2 mg / kg body weight daily Ivermectin orally (3 mg tablets) as a single dose.

#### Category

Treatment - Drugs

### 2

#### Description

Control group will receive only standard treatment. ( protocol-based drugs) Medication does not interfere with meals.

#### Category

Treatment - Drugs

### 3

#### Description

The second intervention group is the patients that will intake 8 mg/kg body weight of metronidazole up to a maximum of 500 mg every 12 hours for 7 days.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faghihi, Chamran and Aliasghar hospitals

##### Full name of responsible person

Hassan Joulaei

##### Street address

School of Medicine, Znd Blvd., Health Policy Research Center

##### City

Shiraz

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14336-71648

##### Phone

+98 71 3230 5410

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joulaei\_h@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Abbas Rezaeianzadeh

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Shiraz University of Medical Science, Zand Blvd.

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##### Email

rezaiana@sums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Hassan Joulaei

##### Position

Assistant professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Others

##### Street address

School of Medicine, Zand Blvd., Health policy Research Center

##### City

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##### Province

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##### Postal code

14336-71348

##### Phone

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences  
**Full name of responsible person**  
Alireza Mirahmadizadeh  
**Position**  
Associated Professor  
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**Other areas of specialty/work**  
Epidemiology  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
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**Other areas of specialty/work**  
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heydari280@yahoo.com

## 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

No - There is not 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

Yes - There is 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

### Title and more details about the data/document

Some of the information, such as the consequences of the study after coding and printing the article, can be shared

### When the data will become available and for how long

The second half of the year 2021

### To whom data/document is available

Researchers from other medical universities

### Under which criteria data/document could be used

Use for joint studies

### From where data/document is obtainable

Deputy for Research, Shiraz University of Medical Sciences

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

Sending a request letter to the Deputy for Research of Shiraz University of Medical Sciences, then deputy order

### Comments