

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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

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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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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

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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