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
City
Shiraz
Province
Fars
Postal code
14336-71648
Phone
+98 71 3230 5410
Email
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
Street address
Shiraz University of Medical Sciense, Zand Blvd.
City
Shiraz
Province
Fars
Postal code
71348-14336
Phone
+98 71 3230 5410
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
Shiraz
Province
Fars
Postal code
14336-71348
Phone
+98 71 3230 5410
Email
joulaei_h@yahoo.com

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

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

Street address
School of Public Health, Al-Zahra Street, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
71348-14336

Phone
00987137251001-9

Email
reza13441@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mohammadreza Heydari

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Shiraz University of Medical Sciense, Zand Blvd.

City
Shiraz

Province
Fars

Postal code
71348-14336

Phone
+98 71 3212 2744

Email
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