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 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)

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+98 51 3854 3031

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person
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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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Latest degree
Specialist

Other areas of specialty/work
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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