Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Evaluating the efficacy and safety of Ivermectin in the treatment of COVID-19 patients: A double-blind randomized controlled trial, phase II

Protocol summary

Study aim
Evaluating the efficacy and safety of Ivermectin in the treatment of COVID-19 patients: A double-blind randomized controlled trial, phase II

Design
Randomize double blind clinical trial, with control group, with a sample size of 60 people, with parallel groups, Phase 2 of Clinical trial

Settings and conduct
The place of the study is Razi hospital and Sina hospital, Ahvaz university of medical science, simple sampling of patients with random allocation , double blind clinical trial, used drug and placebo, supervisor and participants are blind

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age ≥18 years, Laboratory polymerase chain reaction (PCR) confirmed infection with COVID19, Hospitalized, Satisfaction to participate in the study, Acceptance of non-participation in another study before the 28th day of the study. Exclusion criteria: Patients with a history of allergic reaction to Ivermectin Renal dysfunction Liver dysfunction Pregnancy or deciding to get pregnant or breastfeeding

Intervention groups
Intervention group: Receive medication. One ivermectin 14 mg tablet every 12 hours for 3 days. Control group: placebo received a pill quite similar to Ivermectin every 12 hours for 3 days.

Main outcome variables
virus polymerase reaction chain, Number of hospitalization days, hospitfever, dyspnea, , cough, chest CT scan, cell blood count, C-reactive protein

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200404046937N4**
Registration date: **2020-08-06, 1399/05/16**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-11, 1400/03/21**
Update count: **1**

Registration date
2020-08-06, 1399/05/16

Registrant information

Name
Mehran Varnaseri ghandali

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3333 7446

Email address
varnaseri-m@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-30, 1399/05/09

Expected recruitment end date
2020-08-30, 1399/06/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the efficacy and safety of Ivermectin in the treatment of COVID-19 patients: A double-blind randomized controlled trial, phase II

Public title
Evaluating the effect of Ivermectin on covid 19 patients

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age ≥18 years Laboratory polymerase chain reaction (PCR) confirmed infection with COVID19 Hospitalized Satisfaction to participate in the study Acceptance of non-participation in another study before the 28th day of the study
Exclusion criteria:
Patients with a history of allergic reaction to Ivermectin Renal dysfunction Liver dysfunction Pregnancy or deciding to get pregnant or breastfeeding
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into two Therapeutic groups by random method and used 6 blocks method. Individuals are the randomization unit and randomization tools are statistical software, make a random sequence is by using statistical software allocation concealment is by assigning unique codes
Blinding (investigator's opinion)
Double blinded
Blinding description
Double blind: Supervisor and the participants are blind to the prescription drug of the target group and the control group.The drug in both groups is exactly the same in pill form and is in exactly the same packages. The packages are distinguished only by mentioning the number and the list of numbers will be at the disposal of the statistical consultant and then the data will be analyzed.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences
Street address
Ethics committee, main building, Ahvaz jundishapur university of medical science, Golestan
City
Ahvaz
Province
Khouzestan
Postal code
6133744151
Approval date
2020-06-26, 1399/04/06
Ethics committee reference number
IR.AJUMS.REC.1399.322

Health conditions studied

1

Description of health condition studied
COVID 19
ICD-10 code
U07.1
ICD-10 code description
Corona virus infection, unspecified

Primary outcomes

1

Description
Viral diagnostic test
Timepoint
The first day of the study
Method of measurement
Polymerase chain reaction

2

Description
Duration of hospitalization
Timepoint
Time of dyscharge
Method of measurement
Patient file

Secondary outcomes

1

Description
Fever
Timepoint
Daily
Method of measurement
Thermometer

2

Description

Respiratory rate

Timepoint

Daily

Method of measurement

Patient file

3

Description

Dyspnea

Timepoint

Daily

Method of measurement

Patients interview and patient file

4

Description

Cough

Timepoint

Daily

Method of measurement

Patients interview and patient file

5

Description

Cell blood count

Timepoint

The first day of the study and the end of the study

Method of measurement

Lab test

6

Description

C_reactive protein

Timepoint

The first day of the study and the end of the study

Method of measurement

Lab test

7

Description

CT scan

Timepoint

The first day of the study and the end of the study

Method of measurement

CT scan set

Intervention groups

1

Description

Intervention group: Patients in the itervetion group will receive the drug of this study after treatment with routine medications of the disease, which is 14 mg ivermectin tablet, so that the patient will receive one ivermectin tablet every 12 hours for 3 days and then at the time of discharge, Patient symptoms and laboratory data and CT scans will be reviewed.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group will receive placebo after treatment with routine medications, which is quite similar to ivermectin, in that the patient will receive one placebo pill every 12 hours for 3 days, and then at the time of discharge, Patient symptoms and laboratory data and CT scans will be reviewed.d.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital, Ahvaz

Full name of responsible person

Mehran Varnasseri

Street address

Razi hospital, Felestin Ave, Amanieh Ave

City

Ahvaz

Province

Khouzestan

Postal code

6196514941

Phone

+98 61 3333 7446

Email

drvarnaseri.m@gmail.com

2

Recruitment center

Name of recruitment center

Sina hospital, Ahvaz

Full name of responsible person

Mehran Varnaseri

Street address

Sina hospital, 5th Gandomkar st, Koot abdollah Ave

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Email

drvarnaseri.m@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Main building, Ahvaz jundishapur university of medical science, Golstan
City
Ahvaz
Province
Khouzestan
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6135539345
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+98 61 3311 3815
Email
Badavi-m@ajums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Mehran Varnasseri
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
Street address
Razi hospital, Felestin Ave, Amanieh Ave
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Person responsible for scientific inquiries

Contact

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Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

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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