

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Dec 2021

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

Khuzestan

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 discharge

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

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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

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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

Khuzestan

Postal code

6135539345

Phone

+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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mehran Varnasseri

Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Mehran Varnasseri

Position

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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