

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Dec 2023

The efficacy and safety of Ivermectin in patients with COVID-19: a randomized clinical trial

Protocol summary

Study aim

The efficacy and safety of Ivermectin in patients with COVID-19

Design

Controlled clinical trial with parallel groups, open-label, phase 3, 120 patients, simple randomized method

Settings and conduct

This study will be conducted at the Shahid Mohammadi Hospital, Hormozgan University of Medical Sciences, Bandar Abbas. The study population is 60 patients with COVID-19 (30 patients in control group and 30 in study group).

Participants/Inclusion and exclusion criteria

Inclusion criteria: age ≥ 20 years old (weight ≥ 35 kg); positive polymerase chain reaction (PCR) test for COVID-19; non-hospitalized with mild clinical symptoms, and signed informed consent voluntarily and knowingly. Exclusion criteria: underlying diseases (AIDS, asthma, severe liver and kidney disease); history of Loiasis; history of drug allergy to Ivermectin; use of anticoagulants (e.g. warfarin) and ACE inhibitors (e.g. captopril), and pregnancy or breastfeeding.

Intervention groups

Group A will be mild patients receiving standard treatment of COVID-19 according to the Iran Ministry of Health's protocol. Group B will be mild patients receiving, in addition to the standard treatment, a single dose of oral Ivermectin. Group C will be moderate patients receiving standard treatment of COVID-19 according to the Iran Ministry of Health's protocol. Group D will be moderate patients receiving, in addition to the standard treatment, a single dose of oral Ivermectin.

Main outcome variables

For mild patients: clinical symptom improvement; need for hospitalization, and incidence of adverse drug reactions. For moderate patients: length of hospital stay; need for ICU; need for mechanical ventilation, and incidence of adverse drug reactions.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200506047323N6**

Registration date: **2020-11-17, 1399/08/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-17, 1399/08/27**

Update count: **0**

Registration date

2020-11-17, 1399/08/27

Registrant information

Name

Mohammad Fathalipour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-15, 1399/08/25

Expected recruitment end date

2021-02-15, 1399/11/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy and safety of Ivermectin in patients with COVID-19: a randomized clinical trial

Public title

Effect of Ivermectin in treatment of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age ≥ 20 years old Weight ≥ 35 kg Positive polymerase chain reaction (PCR) test for COVID-19 Non-hospitalized mild as well as hospitalized moderate patients Signed informed consent voluntarily and knowingly

Exclusion criteria:

Underlying diseases (AIDS, asthma, severe liver and kidney disease) History of Loiasis History of drug allergy to Ivermectin Use of anticoagulants (e.g. warfarin) and ACE inhibitors (e.g. captopril) Pregnancy or breastfeeding

Age

From **20 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients in both hospitalized (moderate) and outpatient (mild) groups will be randomized into the treatment and control groups based on the following method. Simple randomization method and table of random numbers will be used. If selected number is even, the patient is allocated to treatment group, and if it is odd, the patient is allocated to control group.

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

Ethics committee of Hormozgan University of Medical Sciences

Street address

Jomhuri Eslami Blvd

City

Hormozgan

Province

Hormozgan

Postal code

7919915519

Approval date

2020-11-15, 1399/08/25

Ethics committee reference number

IR.HUMS.REC.1399.410

Health conditions studied

1

Description of health condition studied

COVID-19 disease

ICD-10 code

U07.2

ICD-10 code description

COVID-19, virus not identified

Primary outcomes

1

Description

Length of hospital stay

Timepoint

Until discharge date

Method of measurement

Questionnaire

2

Description

Need for ICU

Timepoint

Until discharge date

Method of measurement

Questionnaire

3

Description

Need for mechanical ventilation

Timepoint

Until discharge date

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Incidence of serious adverse reactions

Timepoint

Before intervention and daily during the study

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: will be mild patients receiving hydroxychloroquine sulfate (Amin Pharmaceutical company, Iran) at a dose of 400 mg twice a day for the first day and 200 mg twice a day for six following days, along with oral Ivermectin (MSD company, France) at a single dose of 0.2 mg/kg.

Category

Treatment - Drugs

2

Description

Control group: will be mild patients receiving hydroxychloroquine sulfate (Amin Pharmaceutical company, Iran) at a dose of 400 mg twice a day for the first day and 200 mg twice a day for six following days.

Category

Treatment - Drugs

3

Description

Intervention group: will be moderate patients receive 200/50 mg Lopinavir/Ritonavir (Heterd company, India) twice a day for the seven days, plus five doses of 44 mcg Interferon beta-1a (CinnaGen, Iran) every other day, plus oral Ivermectin (MSD company, France) at a single dose of 0.2 mg/kg.

Category

Treatment - Drugs

4

Description

Control group: will be moderate patients receive 200/50 mg Lopinavir/Ritonavir (Heterd company, India) twice a day for the seven days, plus five doses of 44 mcg Interferon beta-1a (CinnaGen, Iran) every other day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Mahdi Hasani Azad

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

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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

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Mohammad Fathalipour

Position

Consultant
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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

No - There is not 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

Information regarding the study outcomes will be shared.

When the data will become available and for how long

Data will become available after publication of obtained results

To whom data/document is available

Only academic institutions

Under which criteria data/document could be used

The study protocol or proposal should be approved by Ethics committee of institutions. The rights of authors and sponsors should be respected.

From where data/document is obtainable

M.fathalipour@yahoo.com

What processes are involved for a request to access data/document

A request should be addressed to the Technology and Research Vice-chancellery of Hormozgan University of Medical Sciences and the project executor should be informed.

Comments