Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2021

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
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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
Jomhuri Eslami Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Teamur Aghamolaei
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Jomhuri Eslami Blvd
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Web page address
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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
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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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 informed.
Comments