Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2020

Dose-Finding study of Ivermectin treatment on patients infected with Covid-19:A clinical trial

Protocol summary

Study aim
Dose finding of Ivermectin in control and treatment of COVID-19 patients and suggesting it as an antiviral drug against COVID-19

Design
clinical trial with control group, with parallel groups (5 groups in sum), double blinded, randomized with Randomizer software, with 100 participants.

Settings and conduct
This randomized double blinded multi center clinical trial will be implemented in Qazvin Bu Ali and Velayat hospitals and Khuzestan Razi, Sina and Taleghani hospitals.

Participants/Inclusion and exclusion criteria
1. Patients who test positive for COVID-19 by a commercially available Rapid Antigen Test (RAT) of the nasopharynx. 2. Patients ≥ 20 but < 65 years of age with a temperature (oral) of 100.4°F (38.0°C) or more; patients ≥ 65 years of age with a temperature (oral) of 100.0°F (37.8°C) or more at the first visit, or in the 6 hours prior if antipyretics were taken. 3. Patients with 2 or more of the following symptoms (moderate to severe in intensity) at the time of enrollment: o Cough o Sore throat o Headache o Nasal congestion o Feeling feverish o Body aches o Fatigue

Intervention groups
Control group 1: Standard regimen based on Iran health ministry, Control group 2: Standard regimen based on Iran health ministry plus Placebo, Intervention group 1: Standard regimen based on Iran health ministry plus low dose Ivermectin (200 mcg/kg , PO, Once), Intervention group 2: Standard regimen based on Iran health ministry plus high dose Ivermectin(400 mcg/kg in day1 followed by 200 mcg/kg in day 2 and day 5), Intervention group 3: High dose Ivermectin (400 mcg/kg in day1 followed by 200 mcg/kg in day 2 and day 5)

Main outcome variables
chest CT scan, hospitalization time, CBC and CRP

General information

Reason for update
adding a new intervention group, changing Ivermectin dosages

Acronym

IRCT registration information
IRCT registration number: **IRCT20200408046987N1**
Registration date: **2020-04-27, 1399/02/08**
Registration timing: **prospective**

Last update: **2020-07-21, 1399/04/31**
Update count: **1**

Registration date
2020-04-27, 1399/02/08

Registrant information

Name
Nematollah Gheibi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-04, 1399/02/15

Expected recruitment end date
2020-06-04, 1399/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Dose-Finding study of Ivermectin treatment on patients infected with Covid-19:A clinical trial

Public title
Dose-Finding Study of Ivermectin in the Treatment of COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who test positive for COVID-19 by a commercially available Test Patients ≥ 20 but < 65 years of age with a temperature (oral) of 38°C patients 65 - 80 years of age with a temperature (oral) of 37.8°C Patients with 2 or more of the following symptoms (moderate to severe in intensity) at the time of enrollment: Cough Sore throat Headache Nasal congestion Feeling feverisho Body aches and pains Fatigue (tiredness)

Exclusion criteria:

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **125**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, simple randomization method will be used. A randomized list will be generated by online randomization site. Patients will be allocated to case or control group according to the generated list.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants will receive drug or placebo after signing the consort letter. Practitioner and consequence analyzer will not know about the treatment. Data analyzer will know the groups number only.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qazvin University of Medical Sciences

Street address
Bahonr Blvd. Qazvin University of Medical Sciences

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Province
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Postal code
3419915315

Approval date
2020-04-21, 1399/02/02

Ethics committee reference number
IR.QUMS.REC.1399.017

2

Ethics committee

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3419915315

Approval date
2020-06-09, 1399/03/20

Ethics committee reference number
22144/20/د

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19

Primary outcomes

1

Description
chest image(CT scan)

Timepoint
at hospital clearance

Method of measurement
Patient's profile(CT scan image)

2

Description
hospitalization time

Timepoint

end of intervention

Method of measurement

Hospitalization time

3

Description

CBC and CRP

Timepoint

Before intervention, 7 days after intervention

Method of measurement

Sampling and lab test

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Standard regimen based on Iran health ministry

Category

Treatment - Drugs

2

Description

Intervention group: Standard regimen based on Iran health ministry plus low dose Ivermectin(200 mcg/kg , PO, Once)

Category

Treatment - Drugs

3

Description

Intervention group: Standard regimen based on Iran health ministry plus high dose Ivermectin(200 mcg/kg , PO, interval days:1,2,5)

Category

Treatment - Drugs

4

Description

Control group: Standard regimen based on Iran health ministry plus Placebo,Once in first day. placebo is a simple tablet containing only fillers without any active ingredient and is made by Alborz Darou company.

Category

Treatment - Drugs

5

Description

Intervention group: 400 mcg/kg in day1 followed by 200 mcg/kg in day 2 and day 5

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

Dr. Aliakbar Karami, Dr Elham Zsabganeh

Street address

velayat hospital, taavon square, 22 bahman boulevard, Minoodar town

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2

Recruitment center

Name of recruitment center

Bo ALI hospital

Full name of responsible person

Dr Abbas Allami

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3

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr mohamad jafar yadyad, Dr mehran Varnasseri

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ahwaz

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Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
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Phone
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5

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Dr Ramin Jamshidian, Dr Fatemeh Amini
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Chistasazan Notash Fartak Company Limited.
Full name of responsible person
Dr morteza shakhs niaee
Street address
science and technology park
City
qazvin
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Qazvin
Postal code
3471991984
Phone
+98 28 3336 7100
Email
dr.niaee@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Chistasazan Notash Fartak Company Limited.
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
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Nematollah Gheibi
Position
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Person responsible for updating data

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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