

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)

Phone

+98 28 3332 8212

Email address

ngheibi@qums.ac.ir

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

City

Qazvin

Province

Qazvin

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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Street address

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Postal code

3419915315

Approval date

2020-06-09, 1399/03/20

Ethics committee reference number

22144/20/3

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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Ali32024@yahoo.com

2

Recruitment center**Name of recruitment center**

Bo ALI hospital

Full name of responsible person

Dr Abbas Allami

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Bo Ali Street

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allami9@yahoo.com

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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Shahed1 avenue, Imam Ali square, Ayatollah behbahani boulevard

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ahwaz

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Khuzestan

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4**Recruitment center****Name of recruitment center**

Razi Hospital

Full name of responsible person

Dr mehrdad dargahi, Dr Amir Hooshang Bavarsad

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Province

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dr.mehrdad.dargahi@gmail.com

5**Recruitment center****Name of recruitment center**

Taleghani Hospital

Full name of responsible person

Dr Ramin Jamshidian, Dr Fatemeh Amini

Street address

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6193874473

Phone

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Email

Jamshidian.ramin@gmail.com

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

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qazvin

Province

Qazvin

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Phone

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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

Full name of responsible person

Nematollah Gheibi

Position

Professor of University

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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

Qazvin University of Medical Sciences

Full name of responsible person

Nematollah Gheibi

Position

Professor of University

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Nematollah Gheibi
Position
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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