

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Dec 2023

### 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  $\geq 20$  but  $< 65$  years of age with a temperature (oral) of  $100.4^{\circ}\text{F}$  ( $38.0^{\circ}\text{C}$ ) or more; patients  $\geq 65$  years of age with a temperature (oral) of  $100.0^{\circ}\text{F}$  ( $37.8^{\circ}\text{C}$ ) 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  $\geq 20$  but  $< 65$  years of age with a temperature (oral) of  $38^{\circ}\text{C}$  patients 65 - 80 years of age with a temperature (oral) of  $37.8^{\circ}\text{C}$  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

#### 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

2020-06-09, 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

##### **City**

Qazvin

##### **Province**

Qazvin

##### **Postal code**

3471991984

##### **Phone**

+98 28 3379 0620

##### **Fax**

+98 28 3379 0611

##### **Email**

Ali32024@yahoo.com

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Bo ALI hospital

##### **Full name of responsible person**

Dr Abbas Allami

##### **Street address**

Bo Ali Street

##### **City**

Qazvin

##### **Province**

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##### **Postal code**

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##### **Phone**

+98 28 3333 6001

##### **Email**

allami9@yahoo.com

### 3

#### **Recruitment center**

##### **Name of recruitment center**

Sina Hospital

##### **Full name of responsible person**

Dr mohamad jafar yadyad, Dr mehran Varnasseri

##### **Street address**

Shahed1 avenue, Imam Ali square, Ayatollah behbahani boulevard

##### **City**

ahwaz

##### **Province**

Khuzestan

##### **Postal code**

82213410

##### **Phone**

+98 61 3555 0591

**Email**

2.myadyad@yahoo.com

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

Razi Hospital

**Full name of responsible person**

Dr mehrdad dargahi, Dr Amir Hooshang Bavarsad

**Street address**

Felestin Boulevard, Amaniye

**City**

Ahwaz

**Province**

Khouzestan

**Postal code**

82213410

**Phone**

+98 61 3333 5935

**Email**

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**

Mostalan Boulevard, Amanieh

**City**

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**Province**

Khouzestan

**Postal code**

6193874473

**Phone**

+98 61 3554 0255

**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

**City**

qazvin

**Province**

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

**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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3741999184

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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**  
Professor of University  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Biotechnology  
**Street address**  
Shaid Bahonar Blvd.  
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3741999184  
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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