

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Determination the therapeutic effect of Ivermectin and Sovodak on patients infected with COVID-19: A clinical trial.

#### Protocol summary

##### Study aim

purpose of this study is to Determine the therapeutic effect of Ivermectin and Sovodak on patients infected with COVID-19.

##### Design

clinical trial with control group, with parallel groups (5 groups in sum), double blinded, randomized with Randomizer software, with 150 participants.

##### Settings and conduct

This randomized double blinded clinical trial will be implemented in Qazvin Bu Ali hospital.

##### 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 Ivermectin (400 mcg/kg , PO, Once) and Sovodak(400/60, 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 3 and day 5) and Sovodak(400/60, PO, Once), Intervention group 3: High dose Ivermectin (400 mcg/kg in day1 followed by 200 mcg/kg in day 3 and day 5) and Sovodak(400/60, PO, Once).

##### Main outcome variables

chest CT scan, hospitalization time, CBC and CRP

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200408046987N2**

Registration date: **2020-11-07, 1399/08/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-11-07, 1399/08/17**

Update count: **0**

##### Registration date

2020-11-07, 1399/08/17

##### 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

2020-10-16, 1399/07/25

##### Expected recruitment end date

2020-12-15, 1399/09/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Determination the therapeutic effect of Ivermectin and Sovodak on patients infected with COVID-19: A clinical trial.

#### Public title

Determination the therapeutic effect of Ivermectin and Sovodak on patients infected with 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  $38^{\circ}\text{C}$  and 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 feverish Body aches and pains Fatigue (tiredness)

##### Exclusion criteria:

patients with Immuno deficiency patients under any other antiviral therapy

#### Age

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

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **150**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

In this study, simple randomization method will be used. A randomized list will be generated by Randomizer randomization software. 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

Bahonar Boulevard

##### City

Qazvin

##### Province

Qazvin

##### Postal code

3419915315

#### Approval date

2020-09-20, 1399/06/30

#### Ethics committee reference number

IR.QUMS.REC.1399.228

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

## 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

#### Timepoint

Before intervention, 7 days after intervention

#### Method of measurement

Sampling and lab test

## 4

### Description

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

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

### 3

#### Description

Intervention group: Standard regimen based on Iran health ministry plus Ivermectin (400 mcg/kg , PO, Once) and Sovodak(400/60, PO, Once)

#### Category

Treatment - Drugs

### 4

#### Description

Intervention group: Standard regimen based on Iran health ministry plus high dose Ivermectin(400 mcg/kg in day1 followed by 200 mcg/kg in day 3 and day 5) and Sovodak(400/60, PO, Once)

#### Category

Treatment - Drugs

### 5

#### Description

Intervention group: High dose Ivermectin (400 mcg/kg in day1 followed by 200 mcg/kg in day 3 and day 5) and Sovodak(400/60, PO, Once)

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Bu Ali 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

##### Email

Ali32024@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Akam Tejarat Fartak Farasoo

##### Full name of responsible person

Morteza Shakhs Niaee

##### Street address

Nokhbegan Boulevard, Qazvin 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

Akam Tejarat Fartak Farasoo

#### 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

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Nematollah Gheibi

**Position**

professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Biotechnology

**Street address**

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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

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## Person responsible for updating data

### Contact

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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