

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Oct 2021

### Evaluation effects of the standard regimen along with ivermectin on treatment of corona virus type 2 pneumonia

#### Protocol summary

##### Study aim

The evaluation of ivermectin effects on treatment coronavirus infections

##### Design

Fifty patients with a computerized software allocated to intervention and control group in a randomized parallel open-label phase 3 study

##### Settings and conduct

This is an open-label randomized trial using simple randomization taking place in Kermanshah city, Farabi hospital in patients with coronavirus type-2 pneumonia.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Positive Covid-19 infection patients who are older than 18 years. Less than 14 days elapsed from symptoms initiation. Exclusion criteria: Active liver disease Underlying hematological disease Seizures and encephalopathy Allergies to drugs Pregnancy Breastfeeding Patients who want to participate in the study

##### Intervention groups

In the intervention group, patients receive 150 micrograms per kilogram of ivermectin per day based on their body weight for 7 days along with the standard of care treatments. In the control groups, patients receive the standard of care treatments according to the national guideline.

##### Main outcome variables

Clinical response, virological recovery, recovery time, arterial blood gas, mortality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190624043993N2**

Registration date: **2020-07-12, 1399/04/22**

Registration timing: **prospective**

Last update: **2020-07-12, 1399/04/22**

Update count: **0**

##### Registration date

2020-07-12, 1399/04/22

##### Registrant information

###### Name

foroud shahbazi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3426 6780

###### Email address

foroud08@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-22, 1399/06/01

##### Expected recruitment end date

2021-02-19, 1399/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation effects of the standard regimen along with ivermectin on treatment of corona virus type 2 pneumonia

##### Public title

Evaluation of ivermectin effects on Covid-19

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Definite (clinical and positive PCR) Covid-19 disease Less than 48 hours have passed since the onset of symptoms

**Exclusion criteria:**

Underlying liver disease/hepatitis Underlying hematological disorders Seizures and encephalopathy Known allergies to ivermectin Pregnancy/lactation Patients who themselves or their legal guardians are reluctant to participate or continue clinical trials

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patients are randomly divided into two groups using a computer random number generator with a 1:1 allocation. odd numbers receive ivermectin and standard of care, and even numbers receive standard of care, only.

**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**

Ethical committee of kermanshah university of medical sciences

**Street address**

The vice-chancellor for research and technology, Beheshti Ave, Kermanshah,

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6719851351

**Approval date**

2020-06-16, 1399/03/27

**Ethics committee reference number**

IR.KUMS.REC.1399.289

**Health conditions studied**

1

**Description of health condition studied**

Type-2 coronavirus pneumonia

**ICD-10 code**

U07.2

**ICD-10 code description**

Severe acute respiratory syndrome [SARS]

**Primary outcomes**

1

**Description**

Clinical response

**Timepoint**

Day 7 and 14 after study initiation

**Method of measurement**

Clinical- radiographic

**Secondary outcomes**

1

**Description**

Virological response

**Timepoint**

Day 7

**Method of measurement**

PCR

**Intervention groups**

1

**Description**

Intervention group: Patients will received ivermectin (150mcg/kg/day) along with the standard of care

**Category**

Treatment - Drugs

2

**Description**

Control group: Patients will received the standard of care according to the national guideline.

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Farabi hospital

**Full name of responsible person**

Maria Shirvani

**Street address**

Farabi Medical education center, Dolat-Abad  
Boulevard, Isar Square, Kermanshah, Iran.

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maria\_shirvani@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Farid Najafi

**Street address**

Behesti Blve, Vice chancellor for research and  
technology

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**Email**

farid\_n32@yahoo.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Foroud Shahbazi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

School of pharmacy, Parastar Blve, Kermanshah

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## Person responsible for scientific inquiries

**Contact**

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Kermanshah University of Medical Sciences

**Full name of responsible person**

Maria Shirvani

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

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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