

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Ivermectine effect in treatment of patients with COVID-19 disease

#### Protocol summary

##### Study aim

The effect of Ivermectin on COVID19 virus, studied in vitro and reported by Australian investigators. In this study we intend to verify the efficacy of Ivermectin on the effect of this drug on the on the course of this disease and possible prevention from ICU admission, intubation, and mortality as well as some laboratory hallmarks in this disease.

##### Design

After randomization to two groups of 25 individuals the subjects in treatment group will receive three doses of oral ivermectin 200 micrograms/Kg once every other day for 3 doses plus the usual national protocol of treatment for COVID-19 disease while the control group receive only the national treatment protocol. Clinical trial with be one-way blind, phase 3 trial. Clinical findings and physiological parameters of respiration and treatment outcome as well as the changes in laboratory findings will be recorded. The results of the study will be analyzed using SPSS software.

##### Settings and conduct

In this study, 25 patients with COVID 19 being admitted to ImamReza Hospital who do not meet the exclusion criteria and after matching the similar control group of patients with this disease, in addition to the usual care, will receive three doses of oral ivermectin 200 micrograms / kg once every other day for 3 doses.

##### Participants/Inclusion and exclusion criteria

50 patients with COVID 19 disease with no exclusion criteria Exclusion criteria: history of allergy to ivermectin current helminthic disease Severe CHF, arrhythmia, renal or hepatic failure, end stage malignancy or any other disease on discretion of the physician before randomization and recruitment.

##### Intervention groups

ivermectin

##### Main outcome variables

ICU admission, intubation and mechanical ventilation, and mortality as well as the changes in LDH, CRP, and NLR as a marker of disease activity and predictors of the

outcome in COVID-19 disease.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200818048444N3**

Registration date: **2021-06-20, 1400/03/30**

Registration timing: **retrospective**

Last update: **2021-06-20, 1400/03/30**

Update count: **0**

##### Registration date

2021-06-20, 1400/03/30

##### Registrant information

##### Name

Khalil Ansarin

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3337 8093

##### Email address

dr.ansarin@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-02, 1399/09/12

##### Expected recruitment end date

2021-01-31, 1399/11/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Ivermectine effect in treatment of patients with COVID-19 disease

**Public title**

Ivermectine effect in treatment and prophylaxis of patients and exposed individuals with COVID-19

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with diagnosis of COVID-19 disease

**Exclusion criteria:**

History of allergy to ivermectin, and evidence for current helminthic disease Advanced renal failure with GFR<30 Advanced liver failure Advanced malignancy Severe heart failure or active cardiac arrhythmia

**Age**

No age limit

**Gender**

Both

**Phase**

1

**Groups that have been masked**

No information

**Sample size**

Target sample size: 25

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After determining the eligibility criteria and obtaining informed consent from patients, they will be assigned into the study groups using the Balanced Block Randomization method generated by the designer of the study. The size of the blocks and random sequence generation process will not be clarified for the principal investigator and other researchers so that the allocation concealment will be fully established. In addition, randomization efficacy will be tested at the end of the study and those confounding variables with imbalanced distribution across the study groups will be adjusted through the multivariable models.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Regional Committee on Research Ethics (Studies in

Human Subjects)

**Street address**

No .2, Tabriz University of Medical Science. Golgasht st., Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Approval date**

2020-07-20, 1399/04/30

**Ethics committee reference number**

IR.TBZMED.REC.1399.375

**Health conditions studied****1****Description of health condition studied**

Covid-19 Disease

**ICD-10 code**

U07.1

**ICD-10 code description**

Covid-19 Disease

**Primary outcomes****1****Description**

Patient mortality

**Timepoint**

Within 28 days after the onset of the disease

**Method of measurement**

Physician report

**2****Description**

Transfer to ICU

**Timepoint**

Within 28 days after the onset of the disease

**Method of measurement**

Physician report

**3****Description**

Intubation or mechanical ventilation

**Timepoint**

Within 28 days after the onset of the disease

**Method of measurement**

Physician report

**Secondary outcomes****1****Description**

Improve clinical symptoms

**Timepoint**

Start treatment up to 28 days  
**Method of measurement**  
Physician report

## 2

**Description**  
CRP value  
**Timepoint**  
Start treatment up to 28 days  
**Method of measurement**  
Measurements in serum

## 3

**Description**  
LDH value  
**Timepoint**  
Start treatment up to 28 days  
**Method of measurement**  
Measurements in serum

## 4

**Description**  
NLR value  
**Timepoint**  
Start treatment up to 28 days  
**Method of measurement**  
Measurement with CBCD

## Intervention groups

### 1

**Description**  
Intervention group: 3 doses of oral ivermectin 200 µg / kg once daily for 3 doses  
**Category**  
Treatment - Drugs

### 2

**Description**  
Control group: The patients in the control group will receive the standard treatment recommended by ministry of health for this disease  
**Category**  
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Imam Reza Hospital  
**Full name of responsible person**  
Khalil Ansarin  
**Street address**  
Imam Reza Hospital, Golgasht str.  
**City**

Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5166614756  
**Phone**  
+98 41 3334 7054  
**Email**  
imamreza@tbzmed.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Ministry of Health  
**Full name of responsible person**  
Dr. Harirchi, Iraj  
**Street address**  
Ghods Town, Iran Sima St., between Flamek and Zarafshan, Headquarters of the Ministry of Health, Treatment and Medical Education  
**City**  
Tehran  
**Province**  
East Azarbaijan  
**Postal code**  
**Phone**  
+98 21 8836 3560  
**Email**  
mardomi@behdasht.gov.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Ministry of Health  
**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**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Dr. Khalil Ansarin  
**Position**  
Professor  
**Latest degree**  
Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Tuberculosis and Lung Diseases Research Center,  
Pashmineh Building, University St.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5142954481

**Phone**

+98 41 3337 8093

**Email**

dr.ansarin@gmail.com

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Professor Khalil Ansarin

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Tuberculosis and Lung Diseases Research Center,  
Pashmineh Building, Daneshgah Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5142954481

**Phone**

+98 41 3337 8093

**Fax**

+98 41 3337 8093

**Email**

dr.ansarin@gmail.com

**Web page address**

[https://isid.research.ac.ir/Khalil\\_Ansarin](https://isid.research.ac.ir/Khalil_Ansarin)

**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Khalil Ansarin

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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**Province**

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**Postal code**

5142954481

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data can potentially be shared after unidentified individuals.

**When the data will become available and for how long**

Spring 1400

**To whom data/document is available**

Data is allowed for all researchers after submitting an access request and confirming it

**Under which criteria data/document could be used**

In order to use the data, researchers must first identify and send the required items and data upon request, after which the data will be delivered.

**From where data/document is obtainable**

By email [dr.ansarin@gmail.com](mailto:dr.ansarin@gmail.com) or postal code: 5142954481

**What processes are involved for a request to access data/document**

The researcher must state his request in a letter. After agreeing to his request, the data will be emailed to him in Excel or Spss.

**Comments**