

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Dec 2023

### Evaluation of the effect of oral Ivermectin on the outcome of patients with COVID-19 and compare it with the effect of conventional therapeutics in patients admitted to Ziaeian, Baharloo, Imam Khomeini in the spring and summer 2020

#### Protocol summary

##### Study aim

Considering that COVID-19 is associated with high morbidity and mortality and high public health costs, and given that 100% cure for this disease has not been found, we decided to use the drug Ivermectin, which had promising results in In vitro studies and add to the routine treatment approved by the Ministry of Health and evaluate its effectiveness compared to routine treatment alone.

##### Design

This study is a multi-central blind one-way clinical trial

##### Settings and conduct

Patients with COVID-19 who have been referred to Ziaian, Imam Khomeini and Baharloo hospitals, after examination by a physician and obtaining informed consent, are placed in one of two control or intervention groups without any information and then a medication regimen for them.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 130 patients aged 18 to 50 years old hospitalized in Ziaeian, Baharloo and Imam Khomeini Medical Centers proven cases of COVID-19 After obtaining informed written consent consciously, they are randomly divided into two groups. Exclusion criteria: Severely ill and hospitalized in the intensive care unit, patients who are unable to take oral medications, patients with AST / ALT levels more than 5 times above normal, and pregnant patients do not enter the study.

##### Intervention groups

Patients in the control group are treated with Hydroxychloroquine sulfate and Azithromycin (if there is no cardiac contraindication) according to the protocol of the Ministry of Health. In addition to these drugs, Ivermectin 200 mg (four 3mg tablets in a 60 kg person) is given to the intervention group on the first day and a 3mg tablet is administered every 12 hours for 3 days

from the second day.

##### Main outcome variables

Improving clinical symptoms; reducing the length of hospitalization; improving paraclinical indicators of the disease; lack of response to treatment and hospitalization in the ICU

#### General information

##### Reason for update

##### Acronym

EIC

##### IRCT registration information

IRCT registration number: **IRCT20180922041089N4**

Registration date: **2020-08-23, 1399/06/02**

Registration timing: **retrospective**

Last update: **2020-08-23, 1399/06/02**

Update count: **0**

##### Registration date

2020-08-23, 1399/06/02

##### Registrant information

##### Name

Abolfazl Zendedel

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5517 6031

##### Email address

azendedel@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2020-04-19, 1399/01/31

**Expected recruitment end date**

2020-08-19, 1399/05/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of oral Ivermectin on the outcome of patients with COVID-19 and compare it with the effect of conventional therapeutics in patients admitted to Ziaeiian, Baharloo, Imam Khomeini in the spring and summer 2020

**Public title**

Evaluation of the effect of oral Ivermectin on patients with COVID-19

**Purpose**

Treatment

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

Patients 18 to 50 years Infected by the COVID 19 virus  
Patients with clinical symptoms, history of exposure to the patient and a positive RT-PCR test for Covid 19 from A laboratory or characteristic signs on a CT scan of the chest) with mild to moderate clinical manifestations according to the National Early Warning Score (NEWS) (mild: 1-4 / moderate: 5-6) Obtaining informed written consent consciously

**Exclusion criteria:**

Severely ill and hospitalized in the intensive care unit  
Patients who are unable to take oral medications  
Patients with AST / ALT levels more than 5 times above normal Pregnant patients

**Age**From **18 years** old to **50 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**Target sample size: **130****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be divided into two groups using the black box randomization method (simple). First, patients are selected based on inclusion and exclusion criteria by the treating physician. And then are introduced to the research expert for randomization assignment. Out of 130 patients, he randomly placed 65 people in the intervention group in red and 65 people in the control group in green and informed the therapist. Patients do not know which group they are in.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Patients in this study are blind who enter the study after obtaining informed consent without knowing what group they are in.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

This study is a multi-central blind one-way clinical trial. A total of 130 patients aged 18 to 50 years admitted to Ziaeiian, Baharloo and Imam Khomeini Educational and Medical Centers have been shown to have Covid 19 with mild to moderate clinical manifestations. According to NEWS (mild score 1-4, average score 5-6), after obtaining written consent consciously, they are randomly divided into two groups. The person in charge of collecting patient information during admission and after evaluating drug treatments is unaware of which of the intervention or control groups the patient is in. The control group consisted of 65 patients who were treated with Hydroxychloroquine and azithromycin and the intervention group consisted of 65 patients who, in addition to the above-mentioned regimen, Ivermectin was added to the treatment protocol. This study is part of the phase 3 studies or the classic clinical trial studies.

**Secondary Ids**

empty

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

Iran National Committee For Ethics in Biomedical Research

**Street address**

13th floor, Block A, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Between South Flamek and Zarafshan St., Shahrak Ghods

**City**

Tehran

**Province**

Tehran

**Postal code**

1366736511

**Approval date**

2020-04-29, 1399/02/10

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1399.031

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

Corona virus

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

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

Improving clinical symptoms

**Timepoint**

Daily

**Method of measurement**

National Early Warning Score, (NEWS)

**2****Description**

Reducing the length of hospitalization

**Timepoint**

Daily

**Method of measurement**

Counting

**3****Description**

Improving paraclinical indicators of the disease

**Timepoint**

Daily lymphocyte count - the last day of hospital CT scan

**Method of measurement**

Lymphocyte count - CT scan

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

Lack of response to treatment and hospitalization in the ICU

**Timepoint**

Daily

**Method of measurement**

Assessing clinical manifestations

**Intervention groups****1****Description**

Control group: Patients in the control group are treated with Hydroxychloroquine sulfate and Azithromycin (if there is no cardiac contraindication) according to the protocol of the Ministry of Health

**Category**

Treatment - Drugs

**2****Description**

Intervention group: In the intervention group, in addition

to medication Hydroxychloroquine sulfate and Azithromycin, Ivermectin 200 mg (four 3mg tablets in a 60 kg person) is given to the intervention group on the first day and a 3mg tablet is administered every 12 hours for 3 days from the second day. At the beginning of hospitalization NEWS of patients are checked and ECG is performed, and CBC diff test for lymphopenia, LFT, etc. (according to the ministry protocol) is also performed. Patients are compared after hospitalization for NEWS, clinical signs, and lymphocyte counts daily and CT scan is performed on the last day of hospitalization.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ziaeian Hospital

**Full name of responsible person**

Abolfazl Zendedel

**Street address**

Ziaian Hospital, Abuzar St, Tehran Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1366736511

**Phone**

+98 21 5517 6031

**Email**

research-zia@sina.tums.ac.ir

**2****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Abolfazl Zendedel

**Street address**

End of Keshavarz Boulevard, Dr. Gharib Street

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۱۹۷۳۳۱۴۱

**Phone**

+98 21 6119 2755

**Email**

Imamhospital@tums.ac.ir

**3****Recruitment center****Name of recruitment center**

Baharloo Hospital

**Full name of responsible person**

Saeedreza Jamali moghadam

**Street address**

Railway Square - Behdari Street - Baharloo Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

13399 73111

**Phone**

+98 21 5565 8500

**Email**

baharloo@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammadali Sahraeeian

**Street address**

Keshavarz Blvd - Qods St, Tehran University of  
Medical Sciences

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713137

**Phone**

+98 21 8163 3685

**Email**

vcr@tums.ac.ir

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

There was no financial backer

**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**

Tehran University of Medical Sciences

**Full name of responsible person**

Abolfazl Zendehtdel

**Position**

Ziaian Hospital Education Assistant

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Abuzar Street, Abuzar Square, opposite the 17th  
district of Ziaeean Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1366736511

**Phone**

+98 21 5517 6031

**Fax**

+98 21 5575 1333

**Email**

azendedel@sina.tums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Abolfazl Zendehtdel

**Position**

Ziaian Hospital Education Assistant

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Abuzar Street, Abuzar Square, opposite the 17th  
district of Ziaeean Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1366736511

**Phone**

+98 21 5517 6031

**Fax**

+98 21 5575 1333

**Email**

azendedel@sina.tums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Abolfazl Zendehtdel

**Position**

Ziaian Hospital Education Assistant

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Abuzar Street, Abuzar Square, opposite the 17th district of Ziaeean Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1366736511

**Phone**

+98 21 5517 6031

**Fax**

+98 21 5575 1333

**Email**

azendedel@sina.tums.ac.ir

**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