

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### Comparing the effectiveness of Lopinavir/Ritonavir/Hydroxychloroquine and Atazanavir/Ritonavir/Dolutegravir/Hydroxychloroquine treatment regimens in moderate to severe COVID-19 patients

#### Protocol summary

##### Study aim

Comparison of the effectiveness of Atazanavir/Ritonavir/Dolutegravir/Hydroxychloroquine and Lopinavir/Ritonavir/Hydroxychloroquine treatment regimens in moderate to severe COVID-19 patients based on laboratory and clinical parameters

##### Design

Non-randomized, parallel, phase 3 trial on 60 patients with no control group

##### Settings and conduct

This study is being conducted in order to find a more efficient treatment for COVID-19. All study procedures will be conducted at Rasool-E-Akram general hospital (Tehran,Iran). In this study after a 10 day treatment period, treatment efficacy will be assessed based on clinical and laboratory results and also patients ICU admission, intubation and death rate.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: Having at least three of the disease general symptoms including: Cough, fever of more than 38.5°C, Dyspnea, gastrointestinal symptoms, etc; Or having at least one of the disease characteristics including Oxygen saturation value of less than 93%, disease confirmation based on chest imaging results and a respiratory rate greater than 24 breaths per minute  
Exclusion criteria: Negative COVID-19 specific PCR test result

##### Intervention groups

Patients are divided into two groups in this study: 1) a group receiving Lopinavir (400 mg)\ Ritonavir (100 mg) twice a day and Hydroxychloroquine (400 mg BD for the first day and 200 mg BD afterwards) tablets 1) a group receiving Atazanavir (300 mg)\ Ritonavir (100 mg) twice a day - Dolutegravir (500 mg) once a day and Hydroxychloroquine (400 mg BD for the first day and 200 mg BD afterwards) tablets Treatment period for both groups is 10 days

#### Main outcome variables

Death; ICU admission; Intubation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210214050350N1**

Registration date: **2021-02-22, 1399/12/04**

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

Last update: **2021-02-22, 1399/12/04**

Update count: **0**

##### Registration date

2021-02-22, 1399/12/04

##### Registrant information

##### Name

Saeed Kalantari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6635 2306

##### Email address

sara.minaeian@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-14, 1399/11/26

##### Expected recruitment end date

2021-03-04, 1399/12/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparing the effectiveness of Lopinavir/Ritonavir/Hydroxychloroquine and Atazanavir/Ritonavir/Dolutegravir/Hydroxychloroquine treatment regimens in moderate to severe COVID-19 patients

**Public title**  
Comparing the effectiveness of Kaletra/Hydroxychloroquine and Atazanavir/Dolutegravir/Hydroxychloroquine treatment regimens in COVID-19 treatment

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Having three or more of the following conditions:(1) Cough (2) weakness (3) fever of  $\geq 38.5^{\circ}\text{C}$  (4) Intense fatigue (5) myalgia (6) sore throat (7) Dyspnea (8) Low appetite/Diarrhea/nausea (9) Decreased awareness Or having one or more of the following disease characteristics: (1) Oxygen saturation value of less than 93% (2) disease confirmation based on chest imaging results (3) A respiratory rate greater than 24 breaths per minute  
**Exclusion criteria:**  
Negative COVID-19 specific PCR test result Patients that are well enough to not need hospitalization

**Age**  
No age limit

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**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**  
Ethics committee of Iran University of Medical Sciences  
**Street address**  
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1449614535  
**Approval date**  
2021-01-30, 1399/11/11  
**Ethics committee reference number**  
IR.IUMS.REC.1399.1149

## 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**  
Death  
**Timepoint**  
During treatment  
**Method of measurement**  
Clinical

2

**Description**  
ICU admission  
**Timepoint**  
During treatment  
**Method of measurement**  
Clinical

3

**Description**  
Intubation  
**Timepoint**  
During treatment  
**Method of measurement**  
Clinical

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: This group will receive Atazanavir (300 mg)\ Ritonavir (100 mg) twice a day - Dolutegravir (500 mg) once a day and Hydroxychloroquine (400 mg BD for the first day and 200 mg BD afterwards) tablets for 10 days and during this time their clinical and laboratory parameters will be monitored

#### Category

Treatment - Drugs

### 2

#### Description

Control group: This group will receive Lopinavir (400 mg)\ Ritonavir (100 mg) twice a day and Hydroxychloroquine (400 mg BD for the first day and 200 mg BD afterwards) tablets for 10 days and during this time their clinical and laboratory parameters will be monitored

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasool-E-Akram hospital

##### Full name of responsible person

Donya Maleki

##### Street address

Rasool-E-Akram Hospital, Niayesh St, Satarkhan Av, Tehran, IRAN

##### City

Tehran

##### Province

Tehran

##### Postal code

1445613131

##### Phone

+98 21 6435 2659

##### Email

hrmc@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Seyed Abbas Motevalian

#### Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN

#### City

Tehran

#### Province

Tehran

#### Postal code

1449614535

#### Phone

+98 21 8670 4704

#### Email

amotevalian@iums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran 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

Iran University of Medical Sciences

##### Full name of responsible person

Saeed Kalantari

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Infectious diseases

##### Street address

Rasoul akram hospital, niyayesh St, satarkhan St

##### City

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##### Province

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##### Postal code

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##### Phone

+98 21 6635 2306

##### Fax

##### Email

sara.minaeian@gmail.com

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Saeed Kalantari

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## **Person responsible for updating data**

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Iran University of Medical Sciences

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## **Sharing plan**

### **Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

### **Justification/reason for indecision/not sharing IPD**

Study data will only be provided to requests that were processed through the appropriate university channels

### **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**

Not applicable

### **Data Dictionary**

Not applicable