

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 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

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1445613131

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+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

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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

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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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