Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Feb 2026

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

Public title

Comparing the effectiveness of Kaletra/Hydroxychloroquine and Atazanavir/Dolutegravir/Hydroxychloroquine treatment regiments 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 ≥38.5°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
Tehran
Province
Tehran
Postal code
1449614535
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
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
Street address
Rasoul akram hospital, niyayesh St, satarkhan St
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6635 2306
Fax
Email
sara.minaeian@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Saeed Kalantari
Position
Assistant professor
Latest degree
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Infectious diseases
Street address
Rasoul akram hospital, niyayesh St, satarkhan St
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1449614535
Phone
+98 21 6635 2306
Fax
Email
sara.minaeian@gmail.com

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