

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the efficacy and safety of Atazanavir/Ritonavir plus Hydroxychloroquine regimen with Lopinavir/Ritonavir plus Hydroxychloroquine regimen in patients with moderate COVID-19, A randomized, double-blind study

Protocol summary

Study aim

Comparison of the efficacy and safety of Atazanavir/Ritonavir +HCQ with Lopinavir/Ritonavir +HCQ in patients with moderate COVID-19

Design

A randomized, double-blind, parallel phase 3 clinical trial is conducted on 128 patients with moderate COVID-19. Sealed envelope online software was used to randomize the allocation of treatment to the two intervention arms.

Settings and conduct

Patients dyspnea and O₂Sat less than 94% with possibly lung CT scan evidence of moderate COVID-19 pneumonia (Involvement of a maximum of 3 or 4 lung lobes with an area less than 1/3 size of each lobe or involvement of 1 or 2 lobes with more involvement) and refer to Razi Hospital in Ghaemshahr in the 2020 epidemic, will be enrolled in the study. Researcher and final assessor are blind to the type of intervention and the allocation of treatment is under the supervision of a physician.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Signing a written consent form; Age 18-75 years; Moderate COVID-19 Exclusion criteria: History of hospitalization due to COVID-19; Participate in any other clinical trial of COVID-19 treatment; Patients under mechanical ventilation at baseline; Sensitivity to atazanavir; Active cancer; Immune system compromised; Abnormal baseline ECG; Pregnancy and lactation; Renal failure; Severe liver failure; multi-organ failure; Concomitant use of CYP3A4 inducers

Intervention groups

In group A, 400 mg of hydroxychloroquine on the first day and Kaletra 2 tablets every 12 hours for 5 days, and in group B, hydroxychloroquine 400 mg single dose on the first day and atazanavir/ritonavir daily were administered for at least 5 days.

Main outcome variables

Primary Outcome: Recovery within 10 days of starting treatment
Secondary outcomes: Improvement within 14 days after starting treatment; Survival rate; Number of days hospitalized; Number of days of intubated; Number of days in the ICU

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200328046886N2**

Registration date: **2020-10-12, 1399/07/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-12, 1399/07/21**

Update count: **0**

Registration date

2020-10-12, 1399/07/21

Registrant information

Name

Hamideh Abbaspour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4203 1035

Email address

dr.abbaspour1@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and safety of Atazanavir/Ritonavir plus Hydroxychloroquine regimen with Lopinavir/Ritonavir plus Hydroxychloroquine regimen in patients with moderate COVID-19, A randomized, double-blind study

Public title

Evaluation of the efficacy and safety of Atazanavir/Ritonavir plus Hydroxychloroquine regimen in patients with moderate COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Getting out the informed consent form from all of the patients or their guardian Aged between 18 to 75 Having one of the following symptoms: Dry cough, Severe weakness or fatigue, Dyspnea, Feeling of pain and pressure on the chest, With or without fever greater than 38° C Days from onset of the symptoms equal or less than 7 Definitive diagnosis of moderate COVID-19 based on involvement of up to 3 or 4 pulmonary lobes with an area less than one-third the volume of each lobe or involvement of one or two lobes with a larger area on CT scan O2Sat<94% It is necessary to have all items 1 to 4 and at least one of items 5 and 6

Exclusion criteria:

History of hospitalization because of COVID-19 Participate in any other clinical trial for the treatment of COVID-19 Patients under mechanical ventilation at the baseline Bradycardia Sensitivity to Atazanavir Active cancer Immune deficiency or immune compromised Baseline abnormal ECG Pregnancy and lactation Renal impairment (CLcr<50 mL/min) Severe hepatic impairment (Child-pough C) Multi organ failure Concomitant use of rifampin, carbamazepine, phenytoin

AgeFrom **18 years** old to **75 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **120****Randomization (investigator's opinion)**

Randomized

Randomization description

Before randomization, the effect of confounding factors on the two treatment arms was adjusted. Sealed envelope online software was used to randomize the treatment assignment to the two treatment arms A and B (Keltra/ hydroxychloroquine diet and atazanavir/ritonavir/ hydroxychloroquine diet, respectively) and thus 120 patients were divided into 30 quadri blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

To eliminate Confounding by indication as well as Confounding by severity, the investigator (clinical pharmacy assistant) and patients will be blind to the type of treatment. The treatment will be assigned in accordance with the above block randomization under the supervision of a physician.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee of Mazandaran University of Medical Sciences

Street address

Imam Square, Joybar Three Ways, the beginning of Valiasr Highway, the headquarters of Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Approval date

2020-08-12, 1399/05/22

Ethics committee reference number

IR.MAZUMS.REC.1399.602

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

Effectiveness and safety of Atazanavir in COVID-19

ICD-10 code

U07.1 COVI

ICD-10 code description

Virus Identified

Primary outcomes

1

Description

Recovery within 10 days of starting medication

Timepoint

daily during 10 days from the beginning of intervention

Method of measurement

Measurement of O2 saturation% by pulse oximeter and clinical signs under the supervision of the physician including (no fever - no dyspnea - no cough or improvement compared to baseline - no fatigue or improvement compared to baseline - oral intake for at least 24 hours)

Secondary outcomes

1

Description

survival rate

Timepoint

daily

Method of measurement

By a designed checklist

2

Description

Recovery within 14 days after starting medication

Timepoint

daily until the day 14 after beginning of intervention

Method of measurement

Measurement of O2 saturation% by pulse oximeter and clinical signs under the supervision of the physician including (no fever - no dyspnea - no cough or improvement compared to baseline - no fatigue or improvement compared to baseline - oral intake for at least 24 hours)

3

Description

Number of days hospitalized

Timepoint

daily

Method of measurement

By a designed checklist

4

Description

number of days in ICU

Timepoint

daily

Method of measurement

By a designed checklist

5

Description

number of days intubated

Timepoint

daily

Method of measurement

By a designed checklist

Intervention groups

1

Description

Intervention group: Hydroxychloroquine 400 mg single dose on the first day with atazanavir/ritonavir 100/300 mg daily (2 serving which one contains placebo) for at least 5 days is administered. Atazanavir Considerations: If the patient is receiving PPIs, an interval of at least 12 hours after PPIs and at least 2 hours after H2 blocker should be considered. Take the medicine after or with a meal. Drug interactions with atazanavir including the concomitant use of statins, CYP3A4 inducers, or inhibitors should be considered to dose adjustment.

Category

Treatment - Drugs

2

Description

Intervention group: Hydroxychloroquine 400 mg single dose on the first day with Kaletra (Lopinavir/Ritonavir) (50/200) 2 tablets every 12 hours for at least 5 days is administered.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Hamideh Abbaspour kasgari

Street address

Yusef Reza Ave.

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Web page address

<https://razihospital.mazums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Research and technology department

Street address

Imam Square, Joybar Three Ways, the beginning of Valiasr Highway, the headquarters of Mazandaran University of Medical Sciences

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4815733971

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Hamideh Abbaspour Kasgari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Hamideh Abbaspour Kasgari

Position

Associate professor

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Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Mazandaran University of Medical Sciences

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Position

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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

Yes - There is 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

Yes - There is 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 collected deidentified IPD

When the data will become available and for how long

Starting 1 month after publication

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In situations which the researchers have expressed their willing

From where data/document is obtainable

Email address

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

In a short time after request, will be available with email

Comments