

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of Atazanavir/Ritonavir effect on COVID-19 patients treatment in comparison with Lopinavir / Ritonavir

Protocol summary

Study aim

access to a novel and acceptable treatment. elimination of ineffective treatments. decreasing drug-induced complications. comparison of effect of Atazanavir/Ritonavir and Lopinavir/Ritonavir on inflammatory biomarkers including ESR and CRP. comparison of effect of Atazanavir/Ritonavir and Lopinavir/Ritonavir on respiratory involvement including Pneumonia and COVID-19 induced ARDS comparison of effect of Atazanavir/Ritonavir and Lopinavir/Ritonavir on hospitalization duration. comparison of effect of Atazanavir/Ritonavir and Lopinavir/Ritonavir on drug-induced GI complications. comparison of effect of Atazanavir/Ritonavir and Lopinavir/Ritonavir on mortality/morbidity rate decrease.

Design

This clinical trial is a double-blinded case-control randomized study on 100 patients. Permuted block randomization technique was used for patients randomization.

Settings and conduct

This study will be performed in Bahonar hospital at the first 6 months of the year. Statistical analyses will be accomplished using STATA software. This study is designed double-blinded (patients and physicians). Patients of each group (case or control) will be hospitalized in a specific place and do not have any contact with patients of the opposite group.

Participants/Inclusion and exclusion criteria

Patients between 20-80 years admitted to the hospital whose diseases were confirmed by CT, RT-PCR.

Intervention groups

Atazanavir/Ritonavir treatment group receives novel treatment and Lopinavir/Ritonavir treatment group receives standard treatment. adverse effects and desired effects will be assessed.

Main outcome variables

Clinic and Para clinic findings in COVID-19 patients. Mortality and morbidity rate in COVID-19 patients.

Duration of hospitalization.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200504047298N1**

Registration date: **2020-06-14, 1399/03/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-14, 1399/03/25**

Update count: **0**

Registration date

2020-06-14, 1399/03/25

Registrant information

Name

Zeinab Siami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4602 2136

Email address

z.siami@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-14, 1399/03/25

Expected recruitment end date

2020-06-30, 1399/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Atazanavir/Ritonavir effect on COVID-19 patients treatment in comparison with Lopinavir / Ritonavir

Public title

Effect of Atazanavir/Ritonavirin treatment of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

all COVID-19 patients aged between 20-80

Exclusion criteria:

low blood pressure Nausea Vomiting Dysuria Paleness
Low mental status poor collaboration

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients randomized classification into standard treatment group and case group was performed using permuted block randomization. in this study, four-unit blocks were used. Using R software, a chain of randomized numbers comprising one to six are created to reach the desired sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients, researchers, and health workers were blind. This study is designed double-blinded. Patients of each group (case or control) will be hospitalized in a specific place and do not have any contact with patients of the opposite group. Besides, a member of the research team and a doctor of infectious diseases will prescribe according to assigned treatment codes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University Of Medical Sciences

Street address

Research Department, Safarian Alley, Golshahr Avenue

City

Karaj

Province

Alborz

Postal code

3198764153

Approval date

2020-05-30, 1399/03/10

Ethics committee reference number

IR.ABZUMS.REC.1399.065

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

Use this code when COVID-19 has been confirmed by laboratory testing irrespective of severity of clinical signs or symptoms. Use additional code, if desired, to identify pneumonia or other manifestations.

Primary outcomes

1

Description

COVID-19 patients clinical progression

Timepoint

frequently in hospitalization time

Method of measurement

need to be intubated, body temperature, heart rate, respiratory rate, cough, dyspnea, ICU admission.

2

Description

COVID-19 patients para-clinical progression

Timepoint

frequently in hospitalization time

Method of measurement

O2 saturation, CBC, inflammatory biomarkers (ESR, CRP)

Secondary outcomes

1

Description

O2 saturation

Timepoint

all along the hospitalization

Method of measurement

Pulse oxymeter

2

Description

Temperature

Timepoint

All along the hospitalization

Method of measurement

Thermometer

3

Description

Heart rate

Timepoint

All along the hospitalization

Method of measurement

clinical examination

4

Description

Respiratory rate

Timepoint

All along the hospitalization

Method of measurement

Clinical examination

5

Description

Chest Imaging

Timepoint

Along the hospitalization

Method of measurement

Chest X-ray, CT scan

6

Description

ECG

Timepoint

Along the hospitalization

Method of measurement

12-Lead ECG tool

7

Description

Coughing

Timepoint

along the hospitalization

Method of measurement

inspection and examination

8

Description

ICU admission

Timepoint

Along the hospitalization

Method of measurement

Documents

9

Description

Hospitalization duration

Timepoint

daily

Method of measurement

documents

10

Description

Blood Pressure

Timepoint

Along the hospitalization

Method of measurement

Barometer

Intervention groups

1

Description

Intervention group: Atazanavir/ritonavir treatment group will receive 300/100 mg of each drug for 14 days once a day. It will be prescribed as tablets.

Category

Treatment - Drugs

2

Description

Control group: Lopinavir/ritonavir treatment group will receive 200/50 mg of each drug for 14 days twice a day. It will be prescribed as tablets.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital

Full name of responsible person

Zeinab Siami

Street address

Bahonar Hospital, Shoura Boulivard, Karaj+

City

Karaj

Province

Alborz

Postal code

3154686695

Phone

+98 26 3252 7575

Email

siami_z@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Mohamad Noorisepehr

Street address

Research Office, Safarian Alley, Golshahr Avenue

City

Karaj

Province

Alborz

Postal code

3198764653

Phone

+98 26 3464 3705

Email

Research@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alborz 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

Alborz University of Medical Sciences

Full name of responsible person

Zeinab Siami

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Shoura Boulevard, Shahid Bahonar Hospital

City

Karaj

Province

Alborz

Postal code

3154686695

Phone

+98 26 3252 7575

Email

z.siami@abzums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Zeinab Siami

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Shahid Bahonar Hospital, Shoura Boulevard, Karaj

City

Karaj

Province

Alborz

Postal code

3154686695

Phone

+98 26 3252 7576

Email

z.siami@abzums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Zeinab Siami

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Shahid Bahonar Hospital, Shoura Boulevard, Karaj

City

Karaj

Province

Alborz

Postal code

3154686695

Phone

+98 26 3252 7575

Email

z.siami@abzums.ac.ir

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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All related data except the consent form and analysis-

used codes, would be accessible after final group agreement.

When the data will become available and for how long

for two years after publication

To whom data/document is available

All related data and materials would be accessible for all those who are eager for further information.

Under which criteria data/document could be used

All kinds of analyses would be allowed in case arrangement is made with corresponding author.

From where data/document is obtainable

For further documents access contact with Dr. Siami via email address: z.siami@abzums.ac.ir

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

After arrangement with Dr. Siami, in case of agreement, information and data would be accessible.

Comments