Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Oct 2020

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/Ritanavir and Lopinavir/Ritanavir on inflammatory biomarkers including ESR and CRP. comparison of effect of Atazanavir/Ritanavir and Lopinavir/Ritanavir on respiratory involvement including Pneumonia and COViD-19 induced ARDS comparison of effect of Atazanavir/Ritanavir and Lopinavir/Ritanavir on hospitalization duration. comparison of effect of Atazanavir/Ritanavir and Lopinavir/Ritanavir on drug-induced GI complications. comparison of effect of Atazanavir/Ritanavir and Lopinavir/Ritanavir 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 admmited 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 patinets. 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)

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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

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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+
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Alborz University of Medical Sciences

Full name of responsible person
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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
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

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Person responsible for updating data

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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
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 cia 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, informtaion and data would be accessible.
Comments