Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Dec 2023

Evaluation of efficacy and safety of adding Chlorpromazine to Atazanavir/Ritonavir regimen in the treatment of COVID-19 patients, a randomized double-blind clinical trial

Protocol summary

Study aim

Evaluation of efficacy and safety of adding chlorpromine to Atzanavir/Ritonavir in treatment of admitted patients with covid-19 infection, in order to find the better and safer treatment for this lethal infection.

Design

Randomized parallel group trial with blinded outcome assesment on 100 patients,.Randomization will be done with a 5 digit code from excell software .

Settings and conduct

Patients will be allocated into two groups based on block randomization.Using the Excel software, a 5-digit code will be assigned to each patient. Study drugs will be placed in similar envelopes and patients, physicians and evaluators will not be aware of the type of intervention received. One group will receive atazanavir/ritonavir 300/100 once daily and 25 mg chlorpromazine Three times a day and the other group will receive atazanavir ritonavir 300/100 once daily with 3 doses of placebo for up to 14 days.

Participants/Inclusion and exclusion criteria

the patients with covid 19 infection who admitted in one of university afiliated hospital of Mazandaran University of Medical Sciences,based on clinical findings consistent with covid 19 and confirmed with Rt-PCR or lung Ct findings. treaement regimen consisting of Atazanavir /Ritonavir Spo2 < 93% in room air ages >18 years

Intervention groups

En Intervention group: Atazanavir Ritonavir 300/100 mg once daily and Chlorpromazine 25 mg three times daily up to maximum 14 days Control group: Atazanavir Ritonavir 300/100 mg once daily and placebo three times daily up to maximum 14 days

Main outcome variables

Primary outcome: Daily Spo2 Secondary outcomes: need to ICU admission, admission length in the ICU, admission length in the hospital, mortality rates

General information

Reason for update

Acronym

CIC

IRCT registration information

IRCT registration number: **IRCT20200913048708N1**
Registration date: **2020-10-01, 1399/07/10**
Registration timing: **prospective**

Last update: **2020-10-01, 1399/07/10**
Update count: **0**

Registration date

2020-10-01, 1399/07/10

Registrant information

Name

roya ghasemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3337 8840

Email address

royaghasemian@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-31, 1399/08/10

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of efficacy and safety of adding Chlorpromazine to Atazanavir/Ritonavir regimen in the treatment of COVID-19 patients, a randomized double-blind clinical trial

Public title
Efficacy and safety of Chlorpromazine in the treatment of COVID-19 patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
all admitted patients with covid -19 infection based on clinical findings ,PCR or lung CT abnormality consistent with covid-19 spo2 bellow 93 mmHg age above 18 years old

Exclusion criteria:
patient rejection history of antipsycotic use history of seizure, dementia and parkinson disease Hx of liver disease Hx of feochromocytoma allergy to phenothiazines drug any drug interaction between patients medicines and chlorpromazine pregnancy and lactation Hx of covid treatments bradycardia < 60 /min multi-organ failure

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done using block randomization. 5-digits' codes will be obtained by Excel program and patients will be randomly assigned to intervention and control groups. Each randomization unit will be a block of six blocks including 4 patients in each block (AABB, ABBA, ABAB, BBAA, BAAB and BABA). The sequence of blocks will be determined with a dice that numbers of 1 to 6 written on it. Allocation concealment will be carried out through inserting the study drugs in matt containers with identical appearance and 5 digits' codes written on it.

Blinding (investigator's opinion)
Double blinded

Blinding description
A separate 5-digit code obtained from the computer will be assigned to each patient.The intervention, including the drug or placebo, will be placed in identical containers, and the senior researcher will insert the code on the containers. The researcher and patient will not be aware of the type of intervention received.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics committee of Mazandaran University of Medical Sciences

Street address
Number 8, Shahid moini ave , Amir mazandarani Street , Sari, Iran

City
Sari

Province
Mazandaran

Postal code
48168-13393

Approval date
2020-08-12, 1399/05/22

Ethics committee reference number
IR.MAZUMS.REC.1399.617

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
Patients level of Spo2

Timepoint
daily

Method of measurement
puls oximetr

Secondary outcomes

1

Description
Need to ICU admission

Timepoint
During the study
Method of measurement
Follow up of patient and documentation of the ICU admission

2

Description
Days stayed in the Intensive Care Unit
Timepoint
During the study
Method of measurement
Documenting the days stayed in the Intensive Care Unit

3

Description
Days stayed in the hospital
Timepoint
At the end of the study
Method of measurement
Documentation of the hospital stay according to patients chart

4

Description
Mortality rate
Timepoint
At the end of the study
Method of measurement
Follow up of patients and documentation of the mortality

Intervention groups

1

Description
Intervention group: Patients with covid 19 infection will receive standard treatment of Atazanavir/Ritonavirdrug 300/100 mg (Razavi Pharmaceutical Institute) once daily in addition to chlorpromazine 25 mg (Tehran Shimi Company) three times a day. Maximum time of intervention will be 14 days.
Category
Treatment - Drugs

2

Description
Control group: Patients with covid 19 infection will receive standard treatment of Atazanavir/Ritonavirdrug 300/100 mg (Razavi Pharmaceutical Institute) once daily in addition to Placebo three times a day. Maximum time of intervention will be 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital, Sari
Full name of responsible person
Roya Ghasemian
Street address
n.8, Shahid Moini ave, Amir mazadarani street, Sari, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Majid saeedi
Street address
Research and Technology Deputy, Moallem Square
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Majsaeedi@yahoo.com
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
Ebrahim Salehifar

Position
Professor of Clinical Pharmacy

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Mazandaran University of Medical Sciences

Full name of responsible person
Roya Ghasemian

Position
Associate proffessor of infectious disease

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)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Confidentiality of patients data

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available