

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 May 2021

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 chlorpromazine to Atazanavir/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 assessment 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 affiliated hospital of Mazandaran University of Medical Sciences, based on clinical findings consistent with covid 19 and confirmed with Rt-PCR or lung Ct findings. treatment 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/Ritonavir drug 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/Ritonavir drug 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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roya31gh@yahoo.com

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 updating data

Contact

Name of organization / entity

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Full name of responsible person

Roya Ghasemian

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Associate Professor

Latest degree

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Person responsible for scientific inquiries

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Full name of responsible person

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Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

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City

Sari

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Mazandaran

Postal code

48168-13393

Phone

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