

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### 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

##### **City**

Sari

##### **Province**

Mazandaran

##### **Postal code**

48168-13393

##### **Phone**

+98 11 3337 9692

##### **Email**

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

##### **City**

Sari

##### **Province**

Mazandaran

##### **Postal code**

48168-13393

##### **Phone**

+98 11 3337 9692

##### **Email**

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  
**Street address**  
15 Khordad street -Mahdieh 7 ave  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4818893716  
**Phone**  
+98 11 3340 6746  
**Email**  
Esalehifar52@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Roya Ghasemian  
**Position**  
Associate professor of infectious disease  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Infectious diseases  
**Street address**  
No 8 street  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
48168-13393  
**Phone**

+98 11 3337 9692

### Email

roya31gh@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Roya Ghasemian  
**Position**  
Associate Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Infectious diseases  
**Street address**  
No 8 Street  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
48168-13393  
**Phone**  
+98 11 3337 9692  
**Email**  
roya31gh@yahoo.com

## 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