

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Efficacy and safety evaluation of therapeutic regimen of lopinavir/ritonavir and interferon beta 1b in patients with COVID-19

#### Protocol summary

##### Study aim

efficacy and safety evaluation of interferon beta 1b in therapeutic regimen based on clinical, vital sign and laboratory results in patients with COVID-19

##### Design

This study is a prospective non-randomized clinical trial with control group in phase 2-3 and sample size of 35.

##### Settings and conduct

This trial will be done in Ibn Sina hospital of Sari and including patients who admitted in hospital in separated period of time and received national therapeutic guideline of COVID 19 without interferon beta 1b (within 2 weeks before proposal approval ) and will receive with interferon beta 1b .

##### Participants/Inclusion and exclusion criteria

Patients with more than 18 years old and who are highly suspected or definitely diagnosed with COVID 19 and candidate receiving recommended therapeutic regimen. patients who have allergy to any drugs of therapeutic regimen , pregnancy, lactation, renal and hepatic failure, thyroid disorder and untreated severe depression and seizure history will be excluded.

##### Intervention groups

Intervention group: Standard of care treatment according to the national guidelines for the treatment of COVID-19 including hydroxychloroquine 400 mg stat and lopinavir/ritonavir 200/50 mg two tablets twice daily plus interferon beta 1b for at least 3 doses of 250 mcg subcutaneous. Control: Patients with inclusion criteria and received national therapeutic guideline in separated time before proposal approval.

##### Main outcome variables

Clinical efficacy according to clinical (respiratory system, O2 saturation, fever and cough) and laboratory response (CRP, LDH, CBC) and safety evaluation according to patients tolerably.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190804044429N1**

Registration date: **2020-04-11, 1399/01/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-11, 1399/01/23**

Update count: **0**

##### Registration date

2020-04-11, 1399/01/23

##### Registrant information

##### Name

Monireh Ghazaeian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8863 6864

##### Email address

ghazaeianm@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-25, 1399/01/06

##### Expected recruitment end date

2020-06-25, 1399/04/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy and safety evaluation of therapeutic regimen of lopinavir/ritonavir and interferon beta 1b in patients with COVID-19

## Public title

Interferon beta 1b in COVID-19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All adult patients with highly suspected or confirmed COVID-19 who are candidate for hospitalization and starting therapeutic regimen with lopinavir/ritonavir and hydroxychloroquine

### Exclusion criteria:

History of allergy to any drugs of therapeutic regimen , pregnancy and lactation, renal and hepatic disease, heart failure, uncontrolled depression and untreated thyroid disorders and seizure history.

## Age

From **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Control group in this study is defined as patients who admitted in hospital and received national therapeutic regimen for COVID-19 before the approval of the study proposal compatible with inclusion criteria.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

##### Street address

Ibn Sina Hospital, Pasdaran Blvd, Sari, Mazandaran.

##### City

Sari

##### Province

Mazandaran

##### Postal code

4815733971

##### Approval date

2020-03-24, 1399/01/05

##### Ethics committee reference number

IR.MAZUMS.REC.1399.005

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19 pneumonia

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Clinical response to therapeutic regimen by respiratory rate

#### Timepoint

Daily

#### Method of measurement

physical exam

### 2

#### Description

Clinical response to therapeutic regimen by blood oxygen saturation

#### Timepoint

daily

#### Method of measurement

pulse oximeter

### 3

#### Description

Clinical response to therapeutic regimen by fever

#### Timepoint

daily

#### Method of measurement

thermometer

### 4

#### Description

therapeutic regimen safety

#### Timepoint

daily

#### Method of measurement

patient tolerability

### 5

#### Description

LDH level reduction

**Timepoint**

three times weekly

**Method of measurement**

laboratory test

**6**

**Description**

CRP level reduction

**Timepoint**

three times weekly

**Method of measurement**

laboratory test

**7**

**Description**

lymphocyte count recovery

**Timepoint**

daily

**Method of measurement**

laboratory test

**8**

**Description**

Cough recovery

**Timepoint**

daily

**Method of measurement**

physical exam

**Secondary outcomes**

**1**

**Description**

injection site reactions,

**Timepoint**

Daily

**Method of measurement**

history taking

**2**

**Description**

Hospital stay duration

**Timepoint**

End of treatment

**Method of measurement**

Patient file

**3**

**Description**

Mortality rate

**Timepoint**

Daily

**Method of measurement**

patient file

**4**

**Description**

flu-like symptoms

**Timepoint**

Daily

**Method of measurement**

history taking

**5**

**Description**

liver enzymes changing

**Timepoint**

twice weekly

**Method of measurement**

laboratory test

**Intervention groups**

**1**

**Description**

Intervention group: National therapeutic guideline including hydroxychloroquine 400 mg stat and lopinavir/ritonavir plus 250 mcg interferon beta 1 b subcutaneous injection every other day for at least 3 doses

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Patients with inclusion criteria and received national therapeutic guideline within two weeks before proposal approval.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ibn Sina Hospital

**Full name of responsible person**

Monireh Ghazaeian

**Street address**

Ibn Sina hospital, Pasdaran Blvd, Sari, Mazandaran province.

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**Phone**

+98 11 3334 3011

**Email**

ghazaeianm@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Majid Saeedi

**Street address**

Vice Chancellor for Research, Mazandaran University of Medical Sciences, Joybar 3way , Sari, Iran.

**City**

Sari

**Province**

Mazandaran

**Postal code**

48157-33971

**Phone**

+98 11 3448 4800

**Fax**

+98 11 3335 2725

**Email**

majsaeedi@gmail.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**

Monireh Ghazaeian

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Clinical pharmacy

**Street address**

Ibn Sina hospital, Pasdaran Blvd, Sari, Mazandaran province, Iran.

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Monireh Ghazaeian

**Position**

Assistant professor

**Latest degree**

Specialist

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## Person responsible for updating data

**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

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

### Statistical Analysis Plan

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

### Informed Consent Form

Undecided - It is not yet known if there will be 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

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

The results of trial including analysis data and method of the study

### When the data will become available and for how long

At the time of publication, the data of the study will be available.

### To whom data/document is available

academic researchers, medical team and scientific institutes

### Under which criteria data/document could be used

For research and practical purposes

### From where data/document is obtainable

Dr. Monireh Ghazaeian, Faculty of pharmacy, Mazandaran University of Medical Sciences.

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

The scientific responsible person of the study will reply to the request within 10 days.

### Comments