# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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 Sciennces
**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.
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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.
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Sari
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+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
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## Person responsible for scientific inquiries

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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**
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**