Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 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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Sari
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4815733971
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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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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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Specialist
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Person responsible for updating data

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Specialist
Other areas of specialty/work
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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