Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the efficacy and safety of Favipiravir and Interferon beta compared to Lopinavir/Ritonavir and Interferon beta in patients with COVID-19

Protocol summary

Study aim
Evaluation of the efficacy and safety of Favipiravir and Interferon beta compared to Lopinavir/Ritonavir and Interferon beta in patients with COVID-19

Design
A phase 3 clinical trial with parallel group, open-label, 60 patients, block randomized method

Settings and conduct
This study will be conducted at the Shahid Mohammadi Hospital, Hormozgan University of Medical Sciences, Bandar Abbas.The study population is 60 patients with COVID-19 (30 patients in control group and 30 in study group).

Participants/Inclusion and exclusion criteria
Inclusion criteria:Age ≥18 years, positive polymerase chain reaction (PCR) test for COVID-19, primary clinical symptoms, hospitalized, and signing informed consent. Exclusion Criteria: Underlying diseases, including chronic hepatitis, cirrhosis, cholestatic liver diseases, cholecystitis, and peptic ulcers, acute and chronic renal failure, peptic ulcers, history of allergy to studied drugs, and pregnancy and breastfeeding.

Intervention groups
Group A will be patients receiving Favipiravir and Interferon beta-1a, and Group B will be patients receiving Lopinavir/Ritonavir and Interferon beta-1a.

Main outcome variables
Checking the viral load, fever, O2 saturation, Evaluation of duration of hospitalization, C-reactive protein, Occurrence of adverse drug reactions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200506047323N3**
Registration date: **2020-07-22, 1399/05/01**
Registration timing: **prospective**

Last update: **2020-07-22, 1399/05/01**
Update count: **0**

Registration date
2020-07-22, 1399/05/01

Registrant information

Name
Mohammad Fathalipour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 76 3371 0406

Email address
m.fathalipour@hums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-25, 1399/05/04

Expected recruitment end date
2020-09-25, 1399/07/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy and safety of Favipiravir and Interferon beta compared to Lopinavir/Ritonavir and Interferon beta in patients with COVID-19

Public title

The effects of Favipiravir and Lopinavir/Ritonavir in treatment COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age ≥18 years Positive polymerase chain reaction (PCR) test for COVID-19 Primary clinical symptoms Hospitalized Signing informed consent and willingness of study participant to accept randomization to any assigned treatment arm

Exclusion criteria:
Underlying diseases, including chronic hepatitis, cirrhosis, cholestatic liver diseases, cholecystitis, and peptic ulcers Acute and chronic renal failure Peptic ulcers History of allergy to studied drugs Pregnancy and breastfeeding

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization will be performed (each block consists 6 patients). Allocation sequence and concealment codes will be generated using www.sealedenvelope.com. The closed envelope method will be used to hide the allocation sequence.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences

Street address
Jomhuri Eslami Blvd

City
Bandar Abbas

Province
Hormozgan

Postal code
7919915519

Approval date
2020-07-21, 1399/04/31

Ethics committee reference number
IR.HUMS.REC.1399.225

Health conditions studied

1

Description of health condition studied
COVID-19 disease

ICD-10 code
U07.2

ICD-10 code description
COVID-19, virus not identified

Primary outcomes

1

Description
Viral load

Timepoint
Before intervention and day 7 after the intervention›

Method of measurement
Polymerase chain reaction (PCR) test

2

Description
Body temperature

Timepoint
Before intervention and daily during the study

Method of measurement
Thermometer

3

Description
Oxygen saturation

Timepoint
Before intervention and daily during the study

Method of measurement
Pulse oximeter

Secondary outcomes

1

Description
Duration of hospitalization

Timepoint
Time period from admission to discharge

Method of measurement
Patient's file

2

Description
C-reactive protein

Timepoint
Before intervention and day 7 after the intervention
Method of measurement
C-RP kit

3

Description
Incidence of serious adverse events
Timepoint
Before intervention and daily during the study
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Favipiravir (Zhejiang Hisun, China) plus Interferon beta-1a (CinnaGen, Iran). This group will receive 1600 mg Favipiravir twice a day for the first day and 600 mg twice a day for the following four days, plus five doses of 44 mcg Interferon beta-1a every other day. Other supportive and routine care will be the same in both groups.
Category
Treatment - Drugs

2

Description
Control group: Lopinavir/Ritonavir (Heterd company, India) plus Interferon beta-1a (CinnaGen, Iran). This group will receive 200/50 mg Lopinavir/Ritonavir twice a day for the seven days, plus five doses of 44 mcg Interferon beta-1a every other day. Other supportive and routine care will be the same in both groups.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mohammadi Hospital
Full name of responsible person
Mahdi Hasani Azad
Street address
Jomhuri Eslami Blvd
City
Bandar Abbas
Province
Hormozgan
Postal code
7919915519
Phone
+98 76 3334 7000
Fax
+98 76 3334 5003
Email
shmh@hums.ac.ir
Web page address
http://shmh.hums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Teamur Aghamolaei
Street address
Jomhuri Eslami Blvd
City
Bandar Abbas
Province
Hormozgan
Postal code
7919915519
Phone
+98 76 3333 3280
Fax
+98 76 3334 6994
Email
mail@hums.ac.ir
Web page address
http://hums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Mohammad Fathalipour
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy

Street address
Emam Hossein Blvd
City
Bandar Abbas
Province
Hormozgan
Postal code
7919691982
Phone
+98 76 3371 0406
Fax
+98 76 3371 0389
Email
m.fathalipour@hums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Mohammad Fathalipour
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Emam Hossein Blvd
City
Bandar Abbas
Province
Hormozgan
Postal code
7919691982
Phone
+98 76 3371 0406
Fax
+98 76 3371 0389
Email
m.fathalipour@hums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Mohammad Fathalipour
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Emam Hossein Blvd
City
Bandar Abbas
Province
Hormozgan
Postal code
7919691982
Phone
+98 76 3371 0406
Fax
+98 76 3371 0389
Email
m.fathalipour@hums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Information regarding the study outcomes will be shared
When the data will become available and for how long
Data will become available after publication of obtained results
To whom data/document is available
Only academic institutions
Under which criteria data/document could be used
The study protocol or proposal should be approved by Ethics committee of institutions. The rights of authors and sponsors should be respected.
From where data/document is obtainable
M.fathalipour@yahoo.com, and M.fathalipour@hums.ac.ir
What processes are involved for a request to access data/document
Requests should be addressed to the Technology and Research Vice-chancellery of Hormozgan University of Medical Sciences and the project executor should informed.
Comments