

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 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)

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+98 76 3371 0406

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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

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Jomhuri Eslami Blvd

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Teamur Aghamolaei

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Web page address

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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

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Full name of responsible person

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Position

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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 be informed.

Comments