Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2020

Evaluation of the efficiency and safety of favipiravir + hydroxychloroquine drug regimen in comparison with hydroxychloroquine in hospitalized patients with covid-19

Protocol summary

Study aim

determination of the efficiency and safety of favipiravir+hydroxychloroquine in comparison with hydroxychloroquine in hospitalized patients with covid-19

Design

Clinical trial with control group, double-blind, randomized, phase 3 on 50 patients. Table of random numbers are used for randomization.

Settings and conduct

The study is performed in the wards of Shahid Modarres Hospital. Participants, clinical care providers and evaluators of final outcomes are blinded.

Participants/Inclusion and exclusion criteria

Inpatients with COVID-19 in Shahid Modarres Hospital who have the conditions to enter the study: Inclusion Criteria: -Respiratory Rate(RR)≥30 /min -SpO2<93% on room air -PaO2/FIO2<300 -CT scan Involvement>50% - Diagnosis confirmed by CPR or CT scan -Age more than 18 years - Obtaining the written informed consent from the patient or his/her legal guardian to participate in the clinical trial Exclusion Criteria: -G6PD Deficiency -QT interval more than 450 milliseconds -myasthenia gravis - Pregnancy- Breast Feeding -Severe Renal or Hepatic Failure

Intervention groups

Dosage of the drug in the intervention group: 1600 mg of Favipiravir BD on the first day, 600 mg of Favipiravir BD on the second to fifth day, and concurrent 400 mg of hydroxychloroquine BD on the first day, and 200 mg BD daily on the second to fifth day . The two groups will receive standard treatment (oxygen and, if necessary, antibiotics). Dosage of the drug in the control group: hydroxychloroquine drug 400 mg BD on the first day and 200 mg hydroxychloroquine BD daily on the second to fifth day. Increase the duration of treatment to 10 days according to the doctor's order. The control group will receive placebo instead of Favipiravir.

Main outcome variables

- Discharge criteria include: no fever for 3 days, SpO2> 93%, relative improvement in CXR - All cause Mortality - Need to Mechanical ventilation -Drug Adverse Effect

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200428047228N1**
Registration date: **2020-05-16, 1399/02/27**
Registration timing: **prospective**

Last update: **2020-05-16, 1399/02/27**
Update count: **0**

Registration date

2020-05-16, 1399/02/27

Registrant information

Name

Sanaz Zargar Balaye Jame

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4382 2959

Email address

sanazzargar@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-19, 1399/02/30

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the efficiency and safety of favipiravir + hydroxychloroquine drug regimen in comparison with hydroxychloroquine in hospitalized patients with covid-19

Public title
Evaluation of the efficiency and safety of favipiravir + hydroxychloroquine drug regimen in comparison with hydroxychloroquine in hospitalized patients with covid-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
a- Respiratory Rate(RR)≥30 /min b- SpO2<93% on room air c- PaO2/FIO2<300 d- CT scan Involvement>50% e- Diagnosis confirmed by CPR or CT scan f- Age more than 18 years
Exclusion criteria:
a- G6PD Deficiency b- QT interval more than 450 milliseconds c- myasthenia gravis d- Pregnancy- Breast Feeding e- Severe Renal or Hepatic Failure
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization, Random Number Table
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, health care personnel and evaluators of the final outcome are unaware of the drug given to the intervention and control group .
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
•Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
shahid Modarres Hospital, Saadat Abad, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1998734383
Approval date
2020-04-20, 1399/02/01
Ethics committee reference number
IR.SBMU.RETECH.REC.1399.053

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
COVID-19
ICD-10 code description
U07.1 - COVID-19

Primary outcomes

1

Description
No fever for 3 days
Timepoint
Daily
Method of measurement
Medical Records

2

Description
- SpO2>93%
Timepoint
daily
Method of measurement
Medical Records

3

Description
CXR observation
Timepoint
After the end of the treatment period
Method of measurement
Observation

Secondary outcomes

1

Description
- All cause Mortality
Timepoint
once
Method of measurement
Medical Records

2

Description
- Need to Mechanical ventilation
Timepoint
Daily
Method of measurement
Medical Records

3

Description
Drug Adverse Effect
Timepoint
Daily
Method of measurement
Medical Records

Intervention groups

1

Description
Intervention group: On the first day, 1600 mg of Favipiravir BD, and on the second to fifth day, 600 mg of Favipiravir BD and concurrent hydroxychloroquine, 400 mg BD on the first day and 200 mg hydroxychloroquine BD daily on the second to fifth day. The two groups will receive standard treatment (oxygen and, if necessary, antibiotics).
Category
Treatment - Drugs

2

Description
Control group: hydroxychloroquine, 400 mg BD on the first day and 200 mg hydroxychloroquine BD daily on the second to fifth day. Increasing the duration of treatment to 10 days, according to the doctor's order. The control group will receive placebo instead of Favipiravir.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Modarres Hospital
Full name of responsible person
Dr.Mohammad Fathi
Street address
Shahid Modarres Hospital, Saadat Abad, Tehran, Iran
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Tehran
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1998734383
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m.fathi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Quality Improvement of Intensive Care Research Center- Shahid Beheshti University
Full name of responsible person
Dr.Mohammad Fathi
Street address
Shahid Modarres Hospital, Saadat Abad, Tehran, Iran
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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
Quality Improvement of Intensive Care Research Center- Shahid Beheshti University
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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Mohammad Fathi
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Shahid Modarres Hospital, Saadat abad, Tehran, Iran
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data can be shared after deleting participants' names.
When the data will become available and for how long
The access period will be started six months after the publication of the article.
To whom data/document is available
The data will be available only for academic researchers.
Under which criteria data/document could be used
Only meta-analysis in collaboration with the current study research team will be permitted.
From where data/document is obtainable
Researchers can request data by emailing Dr.Mohammad Fathi(m.fathi@sbmu.ac.ir)
What processes are involved for a request to access data/document
Requested data will be sent by email after consideration and approval by the relevant authorities from Shahid beheshti university.
Comments