Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Evaluation of safety and efficacy of hydroxychloroquine plus favipiravir drug regimen in comparison with hydroxychloroquine plus kaletra on the need for intensive care unit treatment in patients with COVID-19; a randomized, multicenter, parallel groups, open label study

Protocol summary

Study aim
Comparing safety and efficacy of Favipiravir and Kaletra in COVID-19

Design
Randomized parallel group, clinical trial, open label

Settings and conduct
The design is a multicenter clinical trial that will be conducted in 20 centers all over the country.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of COVID-19 based on either ground glass appearance in chest CT scan or positive RT-PCR test for COVID-19; Requiring hospitalization; Patient's age between 16 and 100 years; Signed informed consent form; Exclusion criteria: Receiving other antiviral medications such as (Kaletra, Ribavirin, Oseltamivir); Chronic liver or renal failure; HIV; GI bleeding; Pregnancy; Lactation; QT interval > 500 ms.

Intervention groups
Intervention group: Group receiving Favipiravir plus Hydroxychloroquine. Stat dose of eight 200 mg Favipiravir tablets (total 1600 mg) followed by Favipiravir 600 mg three times a day for 7 days plus Hydroxychloroquine 200mg two times per day for 7 days. Control group: Group receiving Kaletra plus Hydroxychloroquine regimen. Stat dose of two 200 mg Hydroxychloroquine tablets (total 400 mg) followed by Kaletra(Lopinavir/Ritonavir) 200/50 mg two times a day for 7 days.

Main outcome variables
Admission to intensive care unit, In-hopital mortality, length of stay in hospital, Radiological Treatment Response (CT scan), Laboratory Treatment Response (return of blood cell count and CRP values to normal) , Clinical improvement, Oxygen saturation after discontinuation of supplemental oxygen for 5 minutes, Oxygen therapy maximum flow during the day (lit/min), and Adverse and allergic drug reactions

General information

Reason for update
Announcing the Trial completion date

Acronym

IRCT registration information
IRCT registration number: **IRCT20200318046812N1**
Registration date: **2020-04-01, 1399/01/13**
Registration timing: **prospective**

Last update: **2020-09-19, 1399/06/29**
Update count: **6**

Registration date
2020-04-01, 1399/01/13

Registrant information

Name
Mostafa Ghanei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8860 0067

Email address
mghaneister@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-01, 1399/01/13

Expected recruitment end date
2020-06-02, 1399/03/13

Actual recruitment start date

2020-04-02, 1399/01/14

Actual recruitment end date

2020-08-03, 1399/05/13

Trial completion date

2020-08-20, 1399/05/30

Scientific title

Evaluation of safety and efficacy of hydroxychloroquine plus favipiravir drug regimen in comparison with hydroxychloroquine plus kaletra on the need for intensive care unit treatment in patients with COVID-19; a randomized, multicenter, parallel groups, open label study

Public title

Comparison of the safety and efficacy of Favipiravir and kaletra in COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of COVID-19 based on either ground glass appearance in chest CT scan or positive RT-PCR test for COVID-19 Requiring hospitalization because of: Patient's oxygen saturation less than 93% OR Requiring hospitalization because of: GCS score less than 15 OR Requiring hospitalization because of: systolic blood pressure less than 100 or 30 mmHg decrease in systolic blood pressure from the level prior to current illness OR Requiring hospitalization because of: renal failure (creatinine 1.5 times the previous measurement in the last 7 days OR Requiring hospitalization because of: liver failure (AST and ALT 3 times upper limit of normal) Patient's age between 16 and 100 years Signed informed consent form.

Exclusion criteria:

Receiving other antiviral medications such as (Kaletra, Ribavirin, Oseltamivir, ...) Chronic liver failure Chronic Renal Failure Patients with acute problems whose survival is expected to be less than 48 hours HIV patients A history of gastrointestinal bleeding Pregnancy and lactation QT interval exceeds 500 ms

Age

From **16 years** old to **100 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **324**

Actual sample size reached: **424**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use block randomization methods using variable block size of four and six stratified by center. We will use Excel software and rand() function to generate the random sequence. The master randomization list will be kept by the epidemiologist working wit the research team.

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

Iran university of medical sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Next to Milad Tower, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

14665354

Approval date

2020-03-30, 1399/01/11

Ethics committee reference number

IR.IUMS.REC.1399.065

2

Ethics committee

Name of ethics committee

Baqiyatallah university of medical sciences

Street address

Tehran, Vanak Square, Mulla Sadra Street

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2020-03-26, 1399/01/07

Ethics committee reference number

IR.BMSU.REC.1399.017

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description
Admission to intensive care unit
Timepoint
Once (when admitted to intensive care unit)
Method of measurement
Hospital records

Secondary outcomes

1

Description
In-hopital mortality
Timepoint
once
Method of measurement
Patient medical records

2

Description
length of stay in hospital
Timepoint
Once at discharge
Method of measurement
Patient medical records

3

Description
Radiological Treatment Response (CT scan) , more than 50% reduction in the affected area
Timepoint
CT scan will be done twice (once at the time of admission and the second time 10 days after discharge). Assessment will be done comparing the second CT with the first one
Method of measurement
Patient CT scan

4

Description
Laboratory Treatment Response; return of blood cell count and CRP values to normal
Timepoint
Daily
Method of measurement
Laboratory kits

5

Description
Oxygen saturation without supplemental oxygen. Measurement will be done after discontinuation of oxygen therapy for 5 minutes.
Timepoint
4 times a day while in the wards
Method of measurement
Observation

6

Description
Oxygen therapy maximum flow during the day (lit/min)
Timepoint
Daily
Method of measurement
Patient medical records

7

Description
Allergic drug reaction
Timepoint
Daily
Method of measurement
Adverse Drug Reaction forms

8

Description
Adverse drug reactions
Timepoint
Daily
Method of measurement
Adverse Drug Reaction forms

9

Description
Clinical improvement
Timepoint
Daily
Method of measurement
One of the following may happen to the patient: Oxygen saturation reaches above 93% and stays above 93%, the patient does not need oxygen therapy and stays in the same position, discharge by the treating physician

Intervention groups

1

Description
Intervention group: Group receiving Favipiravir plus Hydroxychloroquine. Stat dose of eight 200 mg Favipiravir tablets (total 1600 mg) and stat dose of two 200mg Hydroxychloroquine tablets (total 400 mg) followed by Favipiravir 600 mg three times a day for 7 days. This regimen could be continued for 10 days if necessary according to clinical response of the patient. Other supportive and routine care will be the same in both groups.
Category
Treatment - Drugs

2

Description
Control group: Group receiving Kaletra plus Hydroxychloroquine regimen. Stat dose of two 200 mg

Hydroxychloroquine tablets (total 400 mg) followed by Kaletra(Lopinavir/Ritonavir) 200/50 mg two times a day for 7 days. This regimen could be continued for 10 days if necessary according to clinical response of the patient. Other supportive and routine care will be the same in both groups.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Baqiyatallah university of medical sciences

Full name of responsible person
Dr Behzad Einollahi

Street address
Tehran, Vanak Square, Mulla Sadra Street, Sheikh Bahai Street

City
Tehran

Province
Tehran

Postal code
1435916471

Phone
+98 21 8860 0067

Email
einollahi@numonthly.com

Web page address

2

Recruitment center

Name of recruitment center
Firoozgar Hospital

Full name of responsible person
Dr Farhad Zamani

Street address
Valiasr Square, Karimkhan Bulevard., Behafarin st.,

City
Tehran

Province
Tehran

Postal code
1593747811

Phone
+98 21 8214 1809

Email
biganeh75@gmail.com

3

Recruitment center

Name of recruitment center
Rasoul Akram Hospital

Full name of responsible person
Dr Saeid Kalantari

Street address
Satarkhan, Niayesh St., Maziar Mansouri St.,

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6435 1000

Email
biganeh75@gmail.com

4

Recruitment center

Name of recruitment center
Isfahan Khorshid Hospital

Full name of responsible person
Dr Ramin Sami

Street address
8 Behehst St, Ostandari St

City
Isfahan

Province
Isfehan

Postal code
03132222127

Phone
+98 31 3222 2127

Email
biganeh75@gmail.com

5

Recruitment center

Name of recruitment center
Shahid Beheshti

Full name of responsible person
Dr Mansooreh Momen Heravi

Street address
Qotb ravandi Bulevard

City
Isfahan

Province
Isfehan

Postal code
8715981151

Phone
+98 31 5554 0026

Email
biganeh75@gmail.com

6

Recruitment center

Name of recruitment center
Kosar Hospital

Full name of responsible person
Dr Mohamad Memarian

Street address
Golestan town

City
Semnan

Province

Semnan
Postal code
3519899951
Phone
+98 23 3142 0023
Email
biganeh75@gmail.com

7

Recruitment center
Name of recruitment center
Velaiat Hospital
Full name of responsible person
Dr Mariam Qaraati
Street address
Taavon Square
City
Qazvin
Province
Qazvin
Postal code
02833790610
Phone
+98 28 3379 0627
Email
biganeh75@gmail.com

8

Recruitment center
Name of recruitment center
Emam khomeini Hospital
Full name of responsible person
Dr Roya Qasemian
Street address
Imam Square, Vali Asr Highway
City
Sari
Province
Mazandaran
Postal code
01133361700
Phone
+98 11 3336 1700
Email
biganeh75@gmail.com

9

Recruitment center
Name of recruitment center
Labafinejad Hospital
Full name of responsible person
Dr Shadi Ziaei
Street address
Pasdaran St, 9th Bostan St
City
Tehran
Province
Tehran
Postal code
1666663111
Phone
+98 21 2360 1000
Email
biganeh75@gmail.com

10

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Dr Akram Asghari
Street address
Shahid Beheshti Boulevard
City
Ghoum
Province
Ghoum
Postal code
3719964797
Phone
+98 25 3612 2000
Email
akramasghari11@yahoo.com

11

Recruitment center
Name of recruitment center
Forghani Hospital
Full name of responsible person
Dr Abolfazl Mozafari
Street address
Taleghani Street
City
Ghoum
Province
Ghoum
Postal code
37158
Phone
+98 25 3133 3000
Email
biganeh75@gmail.com

12

Recruitment center
Name of recruitment center
Kamkar Hospital
Full name of responsible person
Dr Javad Khodadadi
Street address
19 Day Street
City
Ghoum
Province
Ghoum
Postal code
37759229
Phone
+98 25 3775 9229
Email

biganeh75@yahoo.com

13

Recruitment center

Name of recruitment center
Rasoul Akram Hospital2
Full name of responsible person
Dr Zeinab Yasin
Street address
Satarkhan, Niayesh St., Maziar Mansouri St.,
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6435 1000
Email
biganeh75@gmail.com

14

Recruitment center

Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Dr Masoud Nazemieh
Street address
University Street, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3334 7054
Email
mnazemiyeh@yahoo.com

15

Recruitment center

Name of recruitment center
Valiasr Hospital
Full name of responsible person
Dr Ahmad Reza Mobaien
Street address
Valiasr Squre
City
Zanjan
Province
Zanjan
Postal code
7797845157
Phone
+98 24 3377 0801
Email
Mobaien1@gmail.com

16

Recruitment center

Name of recruitment center
Firoozabadi Hospital
Full name of responsible person
Dr Farshad Divsalar
Street address
Fadaiyan-e-Islam Street
City
Rey city
Province
Tehran
Postal code
۵۵۹۰۰۲۴۳
Phone
+98 21 5104 8000
Email
Dr.farshaddivsalar@gmail.com

17

Recruitment center

Name of recruitment center
Hajar Hospital
Full name of responsible person
Dr Reza Mosaed
Street address
Valiasr St., Shahid Beheshti Intersection (Abbas Abad)
City
Tehran
Province
Tehran
Postal code
88710294
Phone
+98 21 8871 0294
Email
reza.mosaed1990@gmail.com

18

Recruitment center

Name of recruitment center
Razi Hospital
Full name of responsible person
Dr Lotfallah Davoodi
Street address
Yousef Reza Street
City
Qaemshahr
Province
Mazandaran
Postal code
4765686743
Phone
+98 11 4221 8018
Email
lotfdavoodi@yahoo.com

19

Recruitment center

Name of recruitment center
Ganjavian Hospital
Full name of responsible person
Dr Javad Moazen
Street address
Dezful Andimeshk Highway
City
Dezful
Province
Khouzestan
Postal code
6261684
Phone
+98 61 4242 2040
Email
Dr.moazen@yahoo.com

20

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Dr Maryam Haddadzadeh shoushtari
Street address
Palestine Street
City
Ahvaz
Province
Khouzestan
Postal code
6196514941
Phone
+98 61 3333 5935
Email
m.haddadzadeh_sh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. seyed Abbas Motevalian
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86709
Email
amotevalian@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
50
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

2

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Dr Mostafa Ghanei
Street address
Vanak, Mulla Sadra Street, Sheikh Bahaee Street, Nosrat Alley
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8860 0067
Email
mghaneister@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah University of Medical Sciences
Proportion provided by this source
50
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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Hossein Biganeh

Position
Pharmacy Student
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Vanak, Mulla Sadra Street, Sheikh Bahaee Street, Nosrat Alley
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 31 5472 3386
Email
Biganeh75@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Dr Mostafa Ghanee
Position
Faculty member Baqiyatallah University of Medical Sciences
Latest degree
Subspecialist
Other areas of specialty/work
pulmonologist
Street address
Vanak, Mulla Sadra Street, Sheikh Bahaee Street, Nosrat Alley
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8860 0067
Email
mghaneister@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Hossein Biganeh
Position
Pharmacy Student
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Vanak, Mulla Sadra Street, Sheikh Bahaee Street, Nosrat Alley
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 31 5472 3386
Email
Biganeh75@gmail.com

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
Deidentified IPD related to outcome will be shared.
When the data will become available and for how long
The access period will begin 6 months after publication of the paper
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. Mustafa Qanei (mghaneister@gmail.com) or Dr. Mehdi Bagheri (mbagheri.pharm@gmail.com).
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 Baghiattallah university.
Comments
-