Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The evaluation of safety and efficacy of Favipiravir (ABIDI Pharmaceutical Co, Iran) to shorten the contagiousness in patients with mild to moderate COVID-19

Protocol summary

Study aim

The determination of safety and efficacy of Favipiravir to shorten the contagiousness in patients with mild to moderate COVID-19

Design

Randomised control trial (stratified randomisation based on three recruitment centrs), two arms, parallel, open label, phase 3 with 126 participants(63 in each group) that used the www.sealedenvelope.com website to generate the study' random sequence.

Settings and conduct

Patients with mild to moderate COVID-19 symptoms with positive PCR test for COVID-19 will be referred to one of recruitment centers (Emam khomeni hospital, Loghman hospital, Rasool akram hospital) . In recruitment centers, eligible patients will be allocated to one of two study's groups. Patients will be followed through telephone calls up to 28 days and will give two PCR tests during the follow up period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with mild to moderate COVID-19 symptoms (according to the national guidance definitions) with a positive PCR test for COVID-19
Exclusion criteria: Disorders that investigators believed might put participants in an excess risk or intervene in the Favipiravir absorption process.

Intervention groups

Intervention group: Favipiravir administered orally, that produced by the Dr. Abidi pharmacutical Co, 3200mg (1600mg/ bid) on the first day followed by 1200mg (600mg/bid) daily for the next 4 days (days 1-5). Control group: Hydroxichloroqune (produced by any pharmaceutical company in Iran), 400mg (bid) on the first day, followed by 200mg/day (bid) for the next 4 days (days 1-5) with or without Naproxen and with or without Azythromycin.

Main outcome variables

Proportion of patients with negative test results in the 6th and the 14th day of follow up Time to symptoms recovery (fever, cough) up to 14 days follow up Proportion of patients with recovered symptoms on the 28th day follow up

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201005048936N1**
Registration date: **2020-10-26, 1399/08/05**
Registration timing: **prospective**

Last update: **2020-10-26, 1399/08/05**
Update count: **0**

Registration date

2020-10-26, 1399/08/05

Registrant information

Name

Ayat Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 5660

Email address

aahmadi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-31, 1399/08/10

Expected recruitment end date

2020-12-30, 1399/10/10

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

Scientific title
The evaluation of safety and efficacy of Favipiravir (ABIDI Pharmaceutical Co, Iran) to shorten the contagiousness in patients with mild to moderate COVID-19

Public title
The evaluation of efficacy of Favipiravir in patients with mild to moderate COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with mild to moderate COVID-19 symptoms (According to the national guidance definitions) with positive PCR test for COVID-19 At least 18 years old Less than 10 days from the onset of symptoms
Exclusion criteria:
History of liver disorders (specifically active liver disorders and liver dysfunction included: ALT/AST > 1.5 ULN and ALP > 2.5 ULN and total Bilirubin>1.25 ULN) Allergy to Favipiravir or its ingredients Pregnancy and lactation History of gastrointestinal(GI) disorders such as GI bleeding or GI inflammatory diseases or history of GI surgery that intervene in the Favipiravir absorption process History of active or latent tuberculosis Active infection other than COVID-19 Abnormal metabolism of uric acid/ Gout Abnormal test results in the screening stage that need more clinical assessments Participation in any type of clinical trials in the last 30 days Any psychological disorders that affects patient compliance of the study protocol Any disease or disorder that investigators believed might put participants in an excess risk, if they were included or history of allergy to any antiviral nocleoside-analog drugs with viral RNA polymerase inhibition mechanism Active HBV, HCV HIV or any other known immunological disorders or using immunosuppressive drugs
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **126**
Randomization (investigator's opinion)
Randomized
Randomization description
Stratified randomization depending on recruitment centers will be undertaken. Accordingly, the number of recruited patients would be equal in three recruitment centers. In each center, patients will be equally allocated to study groups, through the simple randomisation method. Random sequence will be produced by using the random generation, available at www.sealedenvelope.com. In doing so, for two study group and total sample size of 126, three block with 42 block size will be defined. Through this method, it will ensured that an equal number of participants in each recruitment center will be obtained. There is no concealment over the randomization process.
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 Imam khomeni hospital in Tehran University of Medical Sciences
Street address
Imam Khomeini Hospital Complex, Tohid Square
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2020-09-30, 1399/07/09
Ethics committee reference number
IR.TUMS.IKHC.REC.1399.215

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
Turning PCR test result into negative
Timepoint
The 6th day and the 14th day after the intervention commence

Method of measurement
Laboratory PCR test for diagnosis of COVID-19

2

Description
Time to recovery of symptoms(fever and cough)
Timepoint
up to 14 days after the intervention commence
Method of measurement
telephone call examination

3

Description
Symptoms recovery(fever and cough)
Timepoint
day 6, day 14 and day 28 after the intervention commence
Method of measurement
telephone call examination

Secondary outcomes

1

Description
incidence of adverse events and adverse reactions
Timepoint
up to the 28th day of follow up
Method of measurement
telephone call examination and/or lab tests

2

Description
ICU admission
Timepoint
up to 28 days after the commence of the intervention
Method of measurement
telephone call follow up

3

Description
Mortality
Timepoint
up to 28 days after the commence of the intervention
Method of measurement
telephone calls follow up

Intervention groups

1

Description
Intervention group:Favipiravir administered orally, produced by the Dr. Abidi pharmacutical Co, Iran, 3200mg (1600/ bid) on the first day followed by 1200mg (600mg/bid) daily for the next 4 days (days 1-5)
Category
Treatment - Drugs

2

Description
Control group: Hydroxichloroqune (produced by any pharmacutical company in Iran), administered orally, 400mg (bid) on the first day followed by 200mg/bid/day for the next 4 days (days 1-5) with or without Naproxen and with or without Azythromycin
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Mahboubeh Hajabdolbaghi
Street address
Building No. 6 (Iran AIDS Research Center)- Imam Khomeini Hospital Complex- end of Keshavar Blvd
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6658 1583
Email
imamhospital@tums.ac.ir
Web page address
http://ikhc.tums.ac.ir/en/#

2

Recruitment center
Name of recruitment center
Loghman hospital
Full name of responsible person
Masoud Mardani
Street address
Loghman hospital - Specific street -Lashgar cross roads
City
Tehran
Province
Tehran
Postal code
1333635445
Phone
+98 21 5541 9005
Email
loghman.hospital@sbmu.ac.ir
Web page address
http://lhmc.sbmu.ac.ir/#

3

Recruitment center
Name of recruitment center

Hazrate Rasoule Akram Hospital

Full name of responsible person
Mahshid Talebi Taher

Street address
Hazrate Rasoole Akram Hospital,Niayesh St,Satarkhan Av,

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 6650 2248

Email
hrmc@iums.ac.ir

Web page address
https://hrmc.iums.ac.ir/en?sid=44

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Dr. Abidi pharmacutical Co.

Full name of responsible person
Ali Rakei

Street address
No.5; 13th str; Bokharest str.

City
Tehran

Province
Tehran

Postal code
1389776363

Phone
+98 21 8870 1600

Email
a.rakei@cobeldarou.com

Web page address
https://abidipharma.com/contact-us/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Dr. Abidi pharmacutical Co.

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ayat Ahmadi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

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Unit 23; No.1547; Nth Kargar str.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Ayat Ahmadi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

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aahmadis@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ayat Ahmadi

Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
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Postal code
1417993357
Phone
+98 21 8897 5660
Fax
Email
aahmadi@tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available