

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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 centres), 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's 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 pharmaceutical Co, 3200mg (1600mg/ bid) on the first day followed by 1200mg (600mg/bid) daily for the next 4 days (days 1-5). Control group: Hydroxichloroquine (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 nucleoside-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 pharmaceutical 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: Hydroxichloroquine (produced by any pharmaceutical 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,
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 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 pharmaceutical 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 pharmaceutical 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
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Other areas of specialty/work
 Epidemiology
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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 Tehran University of Medical Sciences
Full name of responsible person
 Ayat Ahmadi

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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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