Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

Evaluation of the efficacy of Favipiravir in comparison with standard medication on clinical and laboratory findings of COVID-19 patients with moderate severity

Protocol summary

Study aim
Comparison of the therapeutic effect of Favipiravir with Standard medication in COVID-19 patients with moderate-severity referred to the infectious disease clinic of Labbafinejad hospital in 1400

Design
Phase 3 block randomized, open-lable clinical trial with intervention and control groups (allocation ratio 1:1) The sample size of each group is considered about 40 .

Settings and conduct
This study was performed on patients with moderate COVID-19 referred to the infectious diseases clinic of Labbafinejad hospital in 2021. Eligible patients, they are divided into two groups of intervention and control using a random number table. The intervention group, in addition to supportive and symptomatic treatment, receives oral Favipiravir (according to the order mentioned above). The control group recieves standard medication. A trained clinical evaluator then reports patients' recovery on days 1 (start of treatment), 3, 5, and 7. Blood tests are also taken from the patient on days 1 and 7. This is an open-lable study.

Participants/Inclusion and exclusion criteria
Inclusion criteria are: Laboratory confirmation of COVID-19 virus by RT-PCR or COVID-19 compliant imaging evidence; Moderate-severity disease (respiration rate <30 per minute, oxygen saturation> 94%, or pulmonary infiltration <50% in both lungs); and Age over 14 years. Exclusion criteria are: Immunocomprimised patients; Consumption of effective drugs in the treatment of COVID-19; and History anaphylaxis.

Intervention groups
The intervention group, in addition to supportive and symptomatic treatment, receives oral Favipiravir at a dose of 1600 mg every 12 hours for the first day and then 600 mg every 12 hours for the next four days. The control group also receives standard medication.

Main outcome variables
Trend of clinical symptoms

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20211004052664N1**
Registration date: **2021-10-06, 1400/07/14**
Registration timing: **prospective**

Last update: **2021-10-06, 1400/07/14**
Update count: **0**

Registration date
2021-10-06, 1400/07/14

Registrant information
Name
Afshin Bagherzade
Name of organization / entity
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Iran (Islamic Republic of)
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+98 21 2263 2554
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-10-31, 1400/08/09
Expected recruitment end date
2021-12-30, 1400/10/09
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of Favipiravir in comparison with standard medication on clinical and laboratory findings of COVID-19 patients with moderate severity

Public title

The therapeutic effect of Favipiravir in COVID-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Laboratory covfirmation of COVID-19 virus by RT-PCR or imaging findings consistent with COVID-19 Moderate-severity disease (respiratory rate <30 per minute, oxygen saturation > 94% or pulmonaru infiltration < 50% in both lungs) Age above 14 years Willingness to participate in this study

Exclusion criteria:

Immunocompromised patients Pregnancy Consumption of effective drugs in the treatment of COVID-19 in this clinical course History of severe hypersensitivity or anaphylactic shock

Age

From **14 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is a simple randomization that is done in the form of individual random units. The tool used to do this is a random numbers table. The method of constructing a random sequence is that first the researcher selects one of the numbers with his eyes closed and then moves in the right direction. Odd numbers are considered for intervention and even numbers are for control. Random concealment is also performed using sequentially numbered sealed opaque envelopes (SNOSE).

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

Research ethics committees of School of Medicine - Shahid Beheshti University of Medical Sciences

Street address

School of medicine of Shahid Beheshti University of medical sciences, Koodakyar Ave., Daneshjoo Blvd,. Yaman St,. Chamran highway.

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Province

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Postal code

1985717443

Approval date

2021-02-28, 1399/12/10

Ethics committee reference number

IR.SBMU.MSP.REC.1399.750

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19 has been confirmed by laboratory testing irrespective of severity of clinical signs or symptoms

Primary outcomes

1

Description

Body temperature

Timepoint

Days 1 (start of treatment), 3, 5 and 7

Method of measurement

Thermometer

2

Description

Respiratory rate (per minute)

Timepoint

Days 1 (start of treatment), 3, 5 and 7

Method of measurement

Physical examination by physician

3

Description

Oxygen saturation

Timepoint

Days 1 (start of treatment), 3, 5 and 7

Method of measurement

Pulseoxymeter

Secondary outcomes

1

Description
Hospitalization
Timepoint
Seventh day from the beginning of treatment
Method of measurement
Patient medical record

2

Description
Serum CRP level
Timepoint
Days 1 (start of treatment), 3, 5, and 7
Method of measurement
Laboratory report

3

Description
Lymphocyte count
Timepoint
Days 1 (start of treatment), 3, 5, and 7
Method of measurement
Laboratory report

Intervention groups

1

Description
Intervention group: Patients in the intervention group, in addition to standard medication (serum therapy, analgesics, antipyretic, and vitamine), take oral Favipiravir at a dose of 1600 mg every 12 hours for the first day and then 600 mg every 4 hours for 4 days. Favipiravir used is made by Abidi Pharmaceutical Company.
Category
Treatment - Drugs

2

Description
Control group: Patients in the control group receive symptomatic and supportive treatment (analgesic, antipyretic and vitamin) according to the national protocol.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Labbafinejad hospital
Full name of responsible person
Afshin Bagherzade
Street address
9th Boostan St., Pasdaran, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
Shahid Chamran Highway, Yemen St., Shahid Abbas Arabi St. (Parvaneh), Next to Taleghani hospital, Shahid Beheshti University of medical sciences and health services, Headquarters building 2, Floor 5, Deputy of research and technology
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Mpajouhesh@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Bagherzade

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Infectious diseases

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Person responsible for updating data

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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