Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

EVALUATION OF THE EFFECT OF FAVIPIRAVIR ON MANAGEMENT PATIENT WITH COVID-19

Protocol summary

Study aim
Efficacy of Favipiravir in managemant of patient with COVID-19
Design
This is a double blind clinical trial study in phase 3 with 114 patients with COVID19 that randomly devided into 2 groups.
Settings and conduct
This is a double blind clinical trial study with114 patients with positive PCR for COVID19 that have referred to Khansari and Valiasr hospital and they are in subgroup 3 of hospitalization.They will be devided into 2 groups (Favipiravir and control)randomly.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with COVID19 referred to Khansari and Valiasr hospital Patients with COVID19 in subgroup 3 of hospitalization(i.e SPO2 less than 80% or PaO2 less than 60 CmH2O, severe respiratory distress and respiratory rate more than 34 per minute, instable hemodynamic, acid base disturmance, similar to moderate to severe cases) Exclusion criteria: Pregnancy Drug reaction Deterioration of symptoms after drug usage Renal failure manifestation Heart failure manifestation
Intervention groups
Patients in Favipiravir group will be received Favipiravir tablet for 7 days. Patients in control group will be received placebo (flour tablet) for 7 days.
Main outcome variables
severity of COVID19

General information

Reason for update
Acronym
COVID-19
IRCT registration information
IRCT registration number: **IRCT20201028049175N1**
Registration date: **2020-12-12, 1399/09/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-12, 1399/09/22**
Update count: **0**
Registration date
2020-12-12, 1399/09/22

Registrant information
Name
Shamim Valibak
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 86 3417 3502
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-11-21, 1399/09/01
Expected recruitment end date
2021-02-19, 1399/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
EVALUATION OF THE EFFECT OF FAVIPIRAVIR ON MANAGEMENT PATIENT WITH COVID-19

Public title
EVALUATION OF THE EFFECT OF FAVIPIRAVIR ON MANAGEMENT PATIENT WITH COVID-19
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All of patients with COVID19 referred to Valiasr and Khansari hospital All of patients in subgroup 3 of hospitalization

Exclusion criteria:

Patients that present allergic reaction to the drug Patients with deterioration of symptomps after drug usage Renal failure manifestation in patients Heart failure manifestation in patients Pregnancy

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into two groups using a permuted balanced block randomization method with the size of blocks 4 and 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (https://www.sealedenvelope.com/). Concealment is also guaranteed due to the use of permuted balanced block randomization method.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study patients are blind, as one group will receive Favipiravir and control group will receive flour tablet that is similar to Favipiravir.In addition, data analyser is blind about groups of patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Assistance of research and technology, Payambare azam institution, Arak University of Medical Sciences, Sardasht street

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2020-08-02, 1399/05/12

Ethics committee reference number

IR.ARAKMU.REC.1399.179

Health conditions studied

1

Description of health condition studied

Coronavirus disease 2019 (COVID19)

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Severity of coronavirus 2019

Timepoint

Before prescription of drug and then every day until 7 days

Method of measurement

pulse oximetry, resspiratory rate, heart rate, CT scan

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Favipiravir tablet of FUJIFILM company will be given to the patients. The dose is 1600 mg twice daily on first day and days 2–7: 600 mg twice daily.

Category

Treatment - Drugs

2

Description

Control group: Placebo drug (flour tablet) will be given to the patients orally twice daily for 7 days.

Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khansari hospital
Full name of responsible person
Hossein Sarmadian
Street address
The end of Daneshgah street
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2

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Assistance of research and technology of Arak university of medical science-Dr.Alireza Kamali
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
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Assistant professor
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Subspecialist
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Person responsible for scientific inquiries

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Position
lecturer
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Person responsible for updating data

Contact
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General physician non-faculty
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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