Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the therapeutic effect of molnopiravir for patients with Quid 19

Protocol summary

Study aim

1-Determining the clinical effect of Ramdzivir in reducing the load of Covid 19 virus in patients 2- Determining the clinical effect of adding molnopiravir to the treatment regimen containing Ramdzivir in reducing the load of Covid 19 virus in patients 3. Comparison of the clinical effect of Ramdzivir and Ramdzivir with Molnopiravir in reducing the load of Covid virus 19 in patients 4- Determining the side effects of taking Ramdzivir in Covid patients 19

Design

Patients after examination and confirmation of Covid 19 and having entry conditions,According to the simple randomization method, patients are divided into two groups A and B.In the first group, patients receive Ramdzivir in a dose of 200 mg and then 100 mg intravenously daily for up to 5 days.In addition, they receive Mulnopiravir 200 mg every 12 hours for up to 5 days.In the second group, Ramdzivir receive the said dose plus placebo every 12 hours for up to 5 daysThen the tests and ct of the patients are recorded.

Settings and conduct

Patients after examination and confirmation of Covid 19 and having entry conditions,They are included in the study and are prescribed molnopiravir and the patients' symptoms are recorded.

Participants/Inclusion and exclusion criteria

Entry requirements : 1- Patient over 18 years old 2. With moderate Covid 19 who does not need to be hospitalized. No entry conditions: 1. Patients with critical covid 19 2. Gastrointestinal ulcer or inability to swallow oral medication 3. Thrombocytopenia (platelets less than 100 thousand) 4. Liver enzymes more than 3 times normal 5-GFR <30- or need dialysis 6-Bradycardia (HR <50) 7. Patient dissatisfaction to enter the study

Intervention groups

covid-19patients admitted to the intensive care unit and who had severe respiratory failure

Main outcome variables

improve oxygenation improve ct scans

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150107020592N31**
Registration date: **2022-01-09, 1400/10/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-09, 1400/10/19**
Update count: **0**

Registration date

2022-01-09, 1400/10/19

Registrant information

Name

Seyed Mohammad Reza Hashemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 9944

Email address

iran.criticalcare@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-16, 1400/09/25

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the therapeutic effect of molnopiravir for patients with Quid 19

Public title
Evaluation of the therapeutic effect of molnopiravir for patients with Quid 19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patient over 18 years With moderate Covid 19 who does not need to be hospitalized.

Exclusion criteria:
Patients with critical covid 19 Gastrointestinal ulcer or inability to swallow oral medication Thrombocytopenia (platelets less than 100 thousand) Liver enzymes more than 3 times normal GFR <30 or require dialysis Bradycardia (HR <50) Patient dissatisfaction to enter the study

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The groups randomization will performed based on the A and B allocation group. this process will managed by computerizing allocation.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Masih Daneshvari Hospital the Edjucational , Research and Treatment center

Street address
End of Niavaran, Darabadational , Research and Treatment center.

City
Tehran

Province
Tehran

Postal code
1956944413

Approval date
2021-12-09, 1400/09/18

Ethics committee reference number
IR.SBMU.NRITLD.REC.1400.079

Health conditions studied

1

Description of health condition studied
covid-19

ICD-10 code
B34.2

ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
improve oxygenation

Timepoint
0,1,2,3,5,7 after treatment with Molnopiravir

Method of measurement
pulse oximeter

2

Description
improve ct scan

Timepoint
Five days after starting treatment with mulnopiravir

Method of measurement
CT scan unit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients after evaluation and confirmation of Covid 19 and having entry conditions,Enter the study and then patients are divided into two groups A and B based on simple randomization method.In the first group, patients receive Ramdzivir 200 mg loading dose and then 100 mg intravenously daily for up to 5 days. In addition, they receive mulnopiravir at a dose of 200 mg every 12 hours for up to 5 days.In the second group, Ramdzivir receive the said dose plus placebo every 12 hours for up to 5 days.The rest of the drugs used by the patients are the same in the two

groups, then the general condition of the patients, tests and CT scans of the patients are checked.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Masih Daneshvari Hospital the Edjucational , Research and Treatment center

Full name of responsible person
Dr Seyyed Mohamadreza Hashemian

Street address
Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1956944413

Phone
+98 21 2912 3100

Email
iran.criticalcare@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Seyyed Mohamadreza Hashemian

Street address
SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1956944413

Phone
+98 21 2912 3100

Email
iran.criticalcare@yahoo.com

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
Seyed Mohammad Reza Hashemian

Position
استاد

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
تهران، خیابان نیاوران، دارآباد، بیمارستان مسیح دانشوری

City
Tehran

Province
Tehran

Postal code
198396-3113

Phone
+98 912 111 9279

Email
iran.criticalcare@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Seyed Mohammad Reza Hashemian

Position
استاد

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Masih Daneshvari Hospital, Darabad, Niavaran Street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
198396-3113

Phone
+98 912 111 9279

Email
iran.criticalcare@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Seyed Mohammad Reza Hashemian

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Masih Daneshvari Hospital, Darabad, Niavaran Street, Tehran, Iran

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Tehran

Province
Tehran

Postal code
198396-3113

Phone
+98 912 111 9279

Email
iran.criticalcare@yahoo.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
All patient information can be published after deleting the name

When the data will become available and for how long
It will take a month from the time of application

To whom data/document is available
All professors of medical universities in the country

Under which criteria data/document could be used
Help advance science

From where data/document is obtainable
professor hashemian in masih daneshvari hospital

What processes are involved for a request to access data/document
one month

Comments