

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

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

Protocol summary

Study aim

1-Determining the clinical effect of Ramdizivir in reducing the load of Covid 19 virus in patients 2- Determining the clinical effect of adding molnupiravir to the treatment regimen containing Ramdizivir in reducing the load of Covid 19 virus in patients 3. Comparison of the clinical effect of Ramdizivir and Ramdizivir with Molnupiravir in reducing the load of Covid virus 19 in patients 4- Determining the side effects of taking Ramdizivir 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 Ramdizivir in a dose of 200 mg and then 100 mg intravenously daily for up to 5 days. In addition, they receive Molnupiravir 200 mg every 12 hours for up to 5 days. In the second group, Ramdizivir receive the said dose plus placebo every 12 hours for up to 5 days. Then 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 molnupiravir 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-19 patients 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 molnupiravir for patients with Quid 19

Public title

Evaluation of the therapeutic effect of molnupiravir 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 Molnupiravir

Method of measurement

pulse oximeter

2

Description

improve ct scan

Timepoint

Five days after starting treatment with mulnupiravir

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 mulnupiravir 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 Educational ,
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

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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

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Email

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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

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

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تهران، خیابان نیاوران، دارآباد، بیمارستان مسیح دانشوری

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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

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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

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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