Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparing the efficacy of Molnupiravir and placebo on recovery rate in patients with mild COVID-19, a randomized multicenter clinical trial

Protocol summary

Study aim
Evaluation of the efficacy of Molnopiravir in recovery pace of patients with mild COVID-19

Design
Phase 2 and 3 double-blind clinical trials with parallel groups that will be randomized using quadruple blocks and will be performed on 500 patients in two intervention groups with Molnupiravir and placebo groups

Settings and conduct
This research project will be performed in patients with COVID-19 in the initial phase who have referred to the Infectious Diseases Clinic of Baqiyatallah Hospital in Tehran. The study will be double-blinded and patients and outcome assessors will be blinded to the intervention groups. Drugs and placebo will be exactly the same, and drug labels will remain unknown to researchers until the end of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: having a patient in the family; Positive COVID-19 PCR test; Onset of clinical symptoms of the patient less than 3 days; Willing and able to take oral medication; Blood oxygen level above 93%. Exclusion criteria: pregnancy; Breastfeeding; any underlying diseases; history of allergy to antiviral drugs; thrombocytopenia; receiving recent vaccination of COVID-19

Intervention groups
Intervention group: Molnopiravir 200 mg daily for up to five days with diphenhydramine syrup / vitamin C tablets / vitamin D tablets / famotidine tablets 40 mg every 12 hours and naproxen in case of muscle pain and fever. Control group: similar intervention with the difference that they will receive placebo instead of molnopiravir.

Main outcome variables
PCR test and CT number; Fever; dyspnea; Cough; respiratory rate; Serum ESR; Serum CRP; pulse rate; blood pressure; Dry cough

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210914052480N2**
Registration date: **2022-07-07, 1401/04/16**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-07, 1401/04/16**
Update count: **0**

Registration date
2022-07-07, 1401/04/16

Registrant information
Name
Alireza Soleymanitabar
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 8755 4364
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-04-21, 1401/02/01
Expected recruitment end date
2023-03-20, 1401/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparing the efficacy of Molnupiravir and placebo on recovery rate in patients with mild COVID-19, a randomized multicenter clinical trial

Public title
The efficacy of molnupiravir in patients with COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Living in a family with at least one infected person with COVID-19 Not having pulmonary involvement Not having symptoms like chest wall pain and dysnea suggesting pulmonary involvement Positive PCR test of COVID-19 Patient with COVID-19 symptoms lesser than 3 days Patients satisfied with consumption of oral medication Blood oxygen saturation above 93 percents
Exclusion criteria:
Patients under 18 years old Having underlying diseases such as uncontrolled diabetes, uncontrolled blood pressure, liver and heart disease and kidney, heart and liver failure History of any of the diseases including hepatitis B or C, HIV, autoimmune diseases and immunodeficiency History of hepatocellular disease, liver failure and heart failure of liver tests more than 3 times normal History of allergy to antiviral drugs Existence of thrombocytopenia (platelets under 100000) History of recent COVID-19 vaccination lesser than 7 days being pregnant breastfeeding
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **500**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the Block Randomization method will be used using blocks of four in random order. In this method, treatment blocks are moved back and forth randomly, for example, with a block of length 4 and with two treatment groups, there are the following possibilities ABBB, ABAB, ABBA, BABA, BAAB, BBAA By putting these blocks together randomly, a balanced random list of two treatment groups is obtained
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients participating in the clinical trial and individuals collecting patient data will not be aware of the intervention groups. Mulnopiravir and placebo will be exactly the same, and no one will know the contents until the end of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqiyatallah University of Medical Sciences
Street address
Research center; Baqiyatallah University of Medical Sciences; Sheikh-e-bahaei street
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2021-11-20, 1400/08/29
Ethics committee reference number
IR.BMSU.REC.1400.085

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Negative pcr test or increase in CT NUMBER after intervention
Timepoint
Before and after the intervention
Method of measurement
According to the throat sample of patients with Covid-19, which is taken from patients in the same conditions in the specialized virology laboratory of Baqiyatallah Medical Center.

2

Description
fever
Timepoint
Upon arrival and after five days

Method of measurement
with a standard thermometer

3

Description
serum CRP inflammatory factor
Timepoint
Upon arrival and after five days
Method of measurement
By a valid laboratory

4

Description
The level of oxygen saturation in the blood of patients
Timepoint
Upon arrival and after five days
Method of measurement
By standard pulse oximeter

5

Description
dry cough existance
Timepoint
Upon arrival and after five days
Method of measurement
patient report and researcher observe

6

Description
dyspnea
Timepoint
Upon arrival and after five days
Method of measurement
patient report and researcher observe

7

Description
muscular pain
Timepoint
Upon arrival and after five days
Method of measurement
patient report and researcher observe

8

Description
pulse rate
Timepoint
Upon arrival and after five days
Method of measurement
researcher measure

9

Description
respiratory rate
Timepoint
Upon arrival and after five days
Method of measurement
researcher measure

10

Description
blood pressure
Timepoint
Upon arrival and after five days
Method of measurement
researcher measure

11

Description
serum ESR inflammatory factor
Timepoint
Upon arrival and after five days
Method of measurement
By a valid laboratory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The group receiving oral molnopiravir 200 mg daily for up to five days after the intervention, with diphenhydramine syrup / vitamin C tablet / vitamin D tablet / famotidine 40 mg tablet every 12 hours (in case of fever and pain Muscle naproxen 250 mg daily or twice daily will be added)
Category
Treatment - Drugs

2

Description
Control group: This group will receive placebo exactly similar to molnopiravir for five days, with diphenhydramine syrup, vitamin C tablets, vitamin D tablets, famotidine 40mg tablets every 12 hours, and naproxen 250 in case of fever and muscle aches. They will receive it once or twice a day
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah hospital
Full name of responsible person
Morteza Izadi
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Molasadra street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Gholamhosein Alishiri
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Mollasadra street
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+98 21 8755 5250
Email
morteza_izadi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Alireza Soleymanitabar
Position
Medical student, Baqiyatallah University of Medical Sciences
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

Contact
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Morteza Izadi
Position
Ozonetherapy Research Center, Baqiyatallah University of Medical Sciences
Latest degree
Subspecialist
Other areas of specialty/work
Infectious diseases
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Person responsible for updating data

Contact
Name of organization / entity
Students research committee; Baqiyatallah University of Medical Sciences
Full name of responsible person
Alireza Soleymanitabar
Position
Medical student, Baqiyatallah University of Medical Sciences
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Mollasadra st.
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Province

Tehran

Postal code

1435916471

Phone

+98 21 8860 0067

Email

Asoleimanitabar21@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

The data can be used by others without any personal information of patients

When the data will become available and for how long

after data gathering completion

To whom data/document is available

Only people with relevant permissions to use confidential information

Under which criteria data/document could be used

The data can be used for statistical analysis and re-examination

From where data/document is obtainable

Morteza Izadi; access through email: morteza_izadi@yahoo.com

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

After calling or sending an email, the data will be sent if the applicant is valid

Comments