Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the Efficacy of Molnupiravir on Clinical and Laboratory Findings of Patients with moderate COVID-19

Protocol summary

Study aim
Evaluation of the therapeutic effect of Molnupiravir in COVID-19 patients with moderate-severity referred to the infectious disease clinic of Labbafinejad hospital in 2022

Design
Randomized, double-blinded clinical trial, with two intervention and control groups (allocation ratio 1:1).

Settings and conduct
This study was performed on patients with moderate COVID-19 referred to the infectious diseases clinic of Labbafinejad hospital in 2022. 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 Molnupiravir (according to the order mentioned above). The control group recieves standard medication and placebo. 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. In this double-blinded study, the patients and the physician who assessing the clinical outcomes are blind to the patients allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria are: Laboratory confirmation of Coronavirus disease-19 (COVID-19) virus by reverse transcription- polymerase chain reaction (RT-PCR); Moderate-severity disease; Age over 18 years; Patient willingness to participate in the study; Non-pregnant and non-lactating women; No history of anaphylactic shock. Exclusion criteria are: Not completing 5-days medication, all visits and laboratory tests; Development of anaphylactic shock during the study; Occurrence of oral intolerance during clinical course.

Intervention groups
The intervention group, in addition to supportive treatment, receives oral Molnupiravir at a dose of 800 mg every 12 hours for 5 days. The control group also receives standard medication and placebo.

Main outcome variables
Hospitalization during follow-up period.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210901052358N1**
Registration date: **2022-01-03, 1400/10/13**
Registration timing: **prospective**

Last update: **2022-01-03, 1400/10/13**
Update count: **0**

Registration date
2022-01-03, 1400/10/13

Registrant information

Name
Amirreza Keyvanfar

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-21, 1401/01/01

Expected recruitment end date
2022-06-21, 1401/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the Efficacy of Molnupiravir on Clinical and Laboratory Findings of Patients with moderate COVID-19

Public title
The Therapeutic Effect of Molnupiravir in COVID-19 Patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Laboratory confirmation of Coronavirus disease-19 (COVID-19) virus by reverse transcription- polymerase chain reaction (RT-PCR) Moderate-severity disease (respiration rate more than 30 per minute, oxygen saturation more than 94%, or pulmonary infiltration less than 50% in both lungs) Age over 18 years Body mass index less than 40 kilogram per square meters No immunosuppressive diseases, including primary and secondary immunodeficiency, consumption of immunosuppressive drugs, organ transplants, chemotherapy or radiotherapy Patient willingness to participate in the study Existence of oral tolerance Non-pregnant and non-lactating women Not receiving antiviral drugs and other effective drugs in the treatment of COVID-19 in this clinical course No history of severe drug allergy and anaphylactic shock

Exclusion criteria:
Not completing the 5-day treatment period, not completing all visits or laboratory tests Development of severe drug hypersensitivity and anaphylactic shock during the study Occurrence of oral intolerance in the clinical course

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

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)
Double blinded

Blinding description
In this study, patients and physicians who play the role of prescribing medication and evaluating clinical symptoms will be unaware of the classification of patients into intervention and placebo groups (double-blind). Others, including methodologist, statistics specialist, nurses, authors of manuscript, and study designers, will be aware of the classification of patients into the two groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
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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Approval date
2021-11-28, 1400/09/07

Ethics committee reference number
IR.SBMU.RETECH.REC.1400.675

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
Hospitalization during the follow-up period

Timepoint
Seventh day from the beginning of treatment

Method of measurement

Patient medical record

2

Description
Body temperature
Timepoint
Days 1 (start of treatment), 3, 5 and 7
Method of measurement
Thermometer

3

Description
Respiratory rate
Timepoint
Days 1 (start of treatment), 3, 5 and 7
Method of measurement
Physical examination by physician

4

Description
Oxygen saturation
Timepoint
Days 1 (start of treatment), 3, 5 and 7
Method of measurement
Pulseoxymeter

Secondary outcomes

1

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

2

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

3

Description
Platelet count
Timepoint
Days 1 (start of treatment) and 7
Method of measurement
Laboratory report

4

Description
Neutrophil: Lymphocyte ratio
Timepoint
Days 1 (start of treatment) 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 Molnupiravir at a dose of 800 mg every 12 hours for 5 days. Molnupiravir is prepared by Mana Teb Daya Company.
Category
Treatment - Drugs

2

Description
Control group: Patients in the control group, in addition to standard medication (serum therapy, analgesics, antipyretic, and vitamine), take oral placebo every 12 hours for 5 days.
Category
Placebo

Recruitment centers

1

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

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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
Amirreza Keyvanfar
Position
Research assisstant
Latest degree
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Other areas of specialty/work
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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