



COVID-19

Clinical Study

**Learn about the MOVE-NOW
clinical research study for adults
who are more likely to have
serious symptoms from COVID-19**

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About COVID-19

COVID-19 is a disease caused by a virus. Symptoms can feel like a cold, the flu, or pneumonia. Most people who get COVID-19 recover easily, but some can get very sick. Having certain health conditions may make it more likely that you will have serious symptoms or side effects from COVID-19.

Some of these health conditions include:

- Health conditions or medicines that lower your immune system
- Organ transplant
- Bone marrow transplant
- Cancer
- Diabetes

- Lung disease such as asthma or COPD
- HIV
- Heart conditions such as heart failure or a prior heart attack
- Kidney disease or dialysis
- Liver disease such as cirrhosis
- Prior stroke or other neurologic (brain or nerve) conditions

Also, as people get older, starting at about 50 years old, the chance of becoming very sick from COVID-19 gets higher.

People who become very sick with COVID-19 may:

- Need to go to the hospital
- Be in the intensive care unit (ICU) of the hospital
- Need a ventilator (breathing machine) to help them breathe
- Even lose their lives

What are clinical studies?

Clinical trials are research studies that help doctors find out if study drugs (alone or with other treatments) are safe and if they can help prevent, find, or treat diseases or conditions. Clinical trials are carefully controlled research studies that are done to get a closer look at investigational treatments and procedures.

The safety of the people in the studies is the most important factor. There are rules in place to help

protect the rights, safety, and well-being of people who volunteer for research studies.

Before a clinical study can start, a review board or ethics committee must review it. In the U.S., this group is called an IRB or Institutional Review Board. In other countries, this group is called an EC or Ethics Committee. IRBs and ECs are made up of doctors, scientists, and other members of the community. These rules are put in place to make sure studies follow strict scientific and ethical guidelines.

What is the MOVE-NOW study about?

In this study, researchers are testing the investigational drug MK-4482, also known as molnupiravir, in adults who have COVID-19 and who are at high risk for severe illness. This trial is being done to see if the investigational drug is safe and effective, and if it may help prevent symptoms of COVID-19 from lasting a long time or coming back after the original infection.

Can I take part in this study?

You may be able to take part in this study if you're 18 years or older and:

- Have a health condition that may make you more likely to become very sick from COVID-19
- Are not in the hospital for any reason

There are more requirements, which the study doctor will discuss with you. You do not need to currently have COVID-19 to consider taking part in this study.

What is the investigational medicine?

If you take part in this study, you will get the investigational medicine or a placebo. You have an equal chance (like tossing a coin) of getting the investigational medicine or the placebo. Both are tablets taken 2 times a day for 5 days.

A placebo looks like the study medicine, but it has no active ingredients. Researchers use a placebo to help them better understand the effects of the study medicine.

The investigational medicine, molnupiravir, has been approved in some countries to treat adults with COVID-19, but it may not be approved in your country.

What will happen during this study?

You may be in this study for about 6 months if you currently have COVID-19 symptoms and have a positive COVID-19 test.

You may also be able to take part if you do not currently have symptoms of COVID-19. In this case, researchers will ask you to watch yourself for symptoms of COVID-19 until you have COVID-19. This may mean you are in the study for longer than 6 months.

If you take part in the study, you will visit the study clinic about 7 times. You will also have about 3 virtual visits (video or phone) with the study team.

During the study, you will:

- Have certain medical tests, such as:



A physical exam



Your vital signs recorded (your heart rate, temperature, and oxygen level)



Blood tests



Pregnancy tests (if you can get pregnant)

- Answer questions about your symptoms and how they affect your life and activities
- Track your symptoms and when you take the study tablets in an electronic diary

What are the study periods?

There are 4-5 periods in this study:

- **Optional screening** – This will happen if you don't have COVID-19 symptoms. This can last up to several years from your first visit until you have symptoms of COVID-19 and a positive test for COVID-19. The study team will remind you to test for COVID-19 if you have symptoms.
- **Symptomatic screening** – This will happen after symptoms start and you have a positive COVID-19 test. You will have medical tests in at least 1 visit during a time period of about 48 hours to see if you can take part in this study.

- **Intervention** – You will visit the study clinic 3 times over 5 days. You will also take the study medicine during this period.
- **Primary follow-up** – You will visit the study clinic 3 times over 28 days.
- **Extended follow-up** – You will have 3 virtual visits over about 4 months. During these visits, the study doctor or a member of the study team will talk with you about how you are doing.

Is there a cost to take part?

No. There is no cost to:

- Take part in the study
- Get the investigational medicine or placebo
- Have study-related medical tests

Reimbursement may be available for your study-related travel expenses.

To learn more, including the possible risks and benefits of being in this study, please contact:

