



Study participation overview.



The importance of participation.

The COVID-19 pandemic is like nothing we've seen in more than a century. And it's altered each and every one of our lives. Mostly because, to date, no effective vaccine to prevent COVID-19 has been found. Clinical research studies and volunteer study participants are vital to creating a vaccine that will prevent this devastating disease.

Researchers in the Cove Study are trying to find solutions to the current pandemic that has affected the entire world. By enrolling in this study, participants are contributing to a potential solution that could solve this global health crisis.

Study overview.

The purpose of this study is to test an experimental vaccine that may prevent illness after exposure to the SARS-CoV-2 virus, which causes COVID-19.

While enrolled in the Cove Study, participants will need to attend all study visits and comply with all study requirements, which include completing diary entries and immediately alerting the study doctor if they are experiencing symptoms of COVID-19. The study doctor and the study team will provide participants with additional details and answer any questions.

Eligible participants must be:

- **Adults, 18 years of age and older**
- **At high risk of COVID-19 infection (defined as adults whose locations or circumstances put them at greater risk of exposure to the virus responsible for COVID-19, or adults who are at high risk for severe COVID-19 based on age [65 years or older] or underlying medical conditions)**
- **Healthy adults with no previous history of COVID-19, or adults with pre-existing medical conditions that are stable, at the time of screening**
- **Free from prior exposure to an investigational vaccine or treatment for COVID-19**

There are additional eligibility requirements, which the study doctor can explain to you.

About the study vaccine.

Vaccines prepare the immune system to fight infections and prevent illnesses. Certain cells of the immune system produce antibodies (special proteins) that recognize viruses and other pathogens (things that cause disease) and make them harmless.

The vaccine being tested in this study is called mRNA-1273. The study team is testing if the vaccine can help the immune system produce effective antibodies against the SARS-CoV-2 virus so that, in case of infection, the virus does not cause illness.

Typical vaccines for viruses are made from a weakened or inactive virus, but the mRNA-1273 study vaccine is not made from the SARS-CoV-2 virus. It is made from messenger ribonucleic acid (mRNA), a genetic code that tells cells how to make protein. In this case, the protein is a small part of the virus that is thought to help the body's immune system make antibodies to fight the virus.

The vaccine cannot cause infection or make someone sick with COVID-19. Since March 2020, more than 300 people have received the vaccine so far with no serious side effects.

About the placebo.

In order to understand if the study vaccine is effective in preventing the COVID-19 illness or SARS-CoV-2 infection, researchers are comparing the study vaccine to a placebo. A placebo generally looks just like the study drug or study vaccine being tested but contains no active medication or vaccine.

Participants will receive the same level of care from the study team regardless of if they are assigned to the study vaccine or the placebo. Participants will also be closely monitored by the study team if they do have symptoms of COVID-19 at any time throughout their participation.

If a participant is diagnosed with COVID-19 during their participation, the study team will provide them with frequent monitoring because the health and safety of all study participants are our top priorities.

About the Cove Study.

The total length of participation is up to 25 months and includes approximately seven visits to the study site and 24 phone calls.



Participants will have two injection visits, which will happen on the first day and one month later. Participants will get their assigned injections of the study vaccine or placebo. Each participant has a 50% chance of receiving the study vaccine and a 50% chance of receiving the placebo.



Participants will be asked to return to the study site four more times within the next six months.



Participants will be contacted by the study team three times after each injection and then monthly after that to monitor for COVID-19 symptoms. During these phone calls, the study team will check how each participant is feeling and ask for updates on their health.



Participants will also be asked to complete weekly electronic diary entries reporting any COVID-19 symptoms for the duration of the study.



Participants will have one final visit to the study site approximately two years from the date of their second injection.

COVID-19 diagnosis.

If a participant is diagnosed with COVID-19 during study participation, they will have two illness visits, which will occur at the study site. They will also need to attend daily telemedicine visits by videoconference or over the phone for 14 days after the diagnosis visit or until their symptoms have resolved, whichever is later. If a participant is unable to attend a site visit as a result of their health or the coronavirus pandemic, the study team may perform a home visit.

Withdrawing from the Cove Study.

Participants have the right to withdraw from the study at any time for any reason. The study doctor or sponsor also has the right to discontinue a participant at any time in the interest of the participant's safety, or if the participant does not continue to meet eligibility requirements.

**Thank you for your interest
in the Cove Study. Your participation
could make a world of difference.**

**To learn more, contact the
participating site listed here.**

University of Colorado Denver

303-724-0775

moderna

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