Coronavirus Vaccine Trial Now Underway

The trial will enroll healthy volunteers to test the vaccine's safety and ability to trigger an immune response.

March 28, 2020 By Liz Highleyman

Update May 7, 2020: The U.S. Food and Drug Administration completed its review of Moderna's Investigational New Drug application for its coronavirus vaccine candidate, allowing it to proceed to a Phase II trial.

Update March 28, 2020: On March 27, the National Institutes of Health announced that Emory University in Atlanta has been added as a second site for this trial.

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The first human clinical trial of a vaccine for the new coronavirus that causes the respiratory illness COVID-19 started this week in Seattle, according to an announcement from the National Institutes of Health (NIH).

The coronavirus, officially known as SARS-CoV2, continues to spread rapidly. As of March 16, there were more than 179,000 confirmed cases worldwide and more than 4,000 cases in the United States, according to the Johns Hopkins University coronavirus tracker.

While most people have mild cases, the virus can cause severe respiratory disease that to date has led to more than 7,000 deaths. There are currently no approved treatments or vaccines.

This open-label Phase I trial will evaluate an investigational vaccine called mRNA-1273 that was jointly developed by researchers at the NIH's National Institutes of Allergy and Infectious Diseases (NIAID), the biotechnology company Moderna and the Coalition for Epidemic Preparedness Innovations.

Discussing the trial at a virtual special session at the recent Conference on Retroviruses and Opportunistic Infections, NIAID director Anthony Fauci, MD—a key player in the federal government's response to the pandemic—said this was the fastest progression from selection of a suitable viral target sequence to the production of a vaccine candidate for testing.

“Finding a safe and effective vaccine to prevent infection with SARS-CoV-2 is an urgent public health priority,” Fauci said in the NIH statement. “This Phase I study, launched in record speed, is an important first step toward achieving that goal.”

Coronaviruses are spherical viruses with spikes on their surface that bind to human cells and allow the virus to gain entry. The new vaccine uses a messenger RNA (mRNA) genetic sequence from the virus to direct human cells to express a viral spike protein that researchers hope will elicit a robust immune response. Scientists already were working on an investigational vaccine targeting the spike on the MERS coronavirus and were able to quickly modify it to target the SARS-CoV2 spike. The experimental vaccine has shown promise in animal studies.

The first human trial will test different doses of the vaccine (25, 100 or 250 micrograms) to see whether it is safe and whether it induces immune responses against the virus. If the results are promising, it will then move into larger trials to determine whether it protects against infection. Fauci has estimated that the entire process could take at least 12 to 18 months.

This trial is now enrolling 45 healthy adults ages 18 to 55 at Kaiser Permanente Washington Health Research Institute in Seattle. Participants will receive two intramuscular injections of the vaccine in the upper arm about 28 days apart.

The first four participants will receive a single shot of the lowest dose, and the next four will receive the intermediate dose. The researchers will then review preliminary safety data before administering additional injections or vaccinating the remaining people.

Participants will be asked to return to the clinic for follow-up visits between vaccinations and for additional visits for a year after the second shot. They will be monitored for common vaccine side effects, such as fever and injection site soreness, and blood samples will be collected to test for evidence of immune responses.

To be eligible, women may not be pregnant or breast feeding, and women and men of childbearing potential must agree to use effective contraception. The study will not enroll people with certain medical or psychiatric conditions, including respiratory diseases, cardiovascular disease, cancer, HIV, hepatitis B or C, chronic liver disease (including NAFLD/NASH), autoimmune diseases or immune deficiency due to any cause (including use of immune-suppressing drugs, such as cancer chemotherapy or steroids).

While individuals in some of these categories are more likely to develop severe COVID-19 disease—and therefore might seem to need a vaccine more urgently—early trials like this are primarily intended to assess safety, and it is important to test vaccines in healthy people before moving on to higher-risk groups.

For more information about the trial, see ClinicalTrials.gov (study number NCT04283461).

People in the Seattle area interested in joining the study can visit https://corona.kpwashingtonresearch.org.

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