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National Institute of Allergy and Infectious Diseases

NIH Clinical Trial of Investigational Vaccine for COVID-19 Begins

Study Enrolling Seattle-Based Healthy Adult Volunteers

March 16, 2020

Adults in the Seattle area who are interested in joining this study should visit https://corona.kpwashingtonresearch.org/ (https://corona.kpwashingtonresearch.org/) . People who live outside of this region will not be eligible to participate in this trial.

Read the Related Questions & Answers (http://www.niaid.nih.gov/news-events/nih-clinical-trial-investigational-vaccine-covid-19-begins#qa-section)

A Phase 1 clinical trial evaluating an investigational vaccine designed to protect against coronavirus disease 2019 (COVID-19) has begun at Kaiser Permanente Washington Health Research Institute (KPWHRI) in Seattle. The National Institute of Allergy and Infectious Diseases (NIAID) (https://www.niaid.nih.gov/diseases-conditions/coronaviruses), part of the National Institutes of Health, is funding the trial. KPWHRI is part of NIAID's Infectious Diseases Clinical Research Consortium. The open-label trial will enroll 45 healthy adult volunteers ages 18 to 55 years over approximately 6 weeks. The rst participant received the investigational vaccine today.

The study is evaluating different doses of the experimental vaccine for safety and its ability to induce an immune response in participants. This is the rst of multiple steps in the clinical trial process for evaluating the potential bene t of the vaccine.

The vaccine is called mRNA-1273 and was developed by NIAID scientists and their collaborators at the biotechnology company Moderna, Inc., based in Cambridge, Massachusetts. The Coalition for Epidemic Preparedness Innovations (CEPI) supported the manufacturing of the vaccine candidate for the Phase 1 clinical trial.

“Finding a safe and effective vaccine to prevent infection with SARS-CoV-2 is an urgent public health priority,” said NIAID Director Anthony S. Fauci, M.D. “This Phase 1 study, launched in record speed, is an important first step toward achieving that goal.”

Infection with SARS-CoV-2, the virus that causes COVID-19, can cause a mild to severe respiratory illness and include symptoms of fever, cough and shortness of breath. COVID-19 cases were first identified in December 2019 in Wuhan, Hubei Province, China. As of March 15, 2020, the World Health Organization (WHO) (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports) has reported 153,517 cases of COVID-19 and 5,735 deaths worldwide. More than 2,800 confirmed COVID-19 cases and 58 deaths have been reported in the United States as of March 15, according to the Centers for Disease Control and Prevention (CDC) (https://www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html) .

Currently, no approved vaccines exist to prevent infection with SARS-CoV-2.

The investigational vaccine was developed using a genetic platform called mRNA (messenger RNA). The investigational vaccine directs the body’s cells to express a virus protein that it is hoped will elicit a robust immune response. The mRNA-1273 vaccine has shown promise in animal models, and this is the first trial to examine it in humans.

Scientists at NIAID’s Vaccine Research Center (VRC) and Moderna were able to quickly develop mRNA-1273 because of prior studies of related coronaviruses that cause severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). Coronaviruses are spherical and have spikes protruding from their surface, giving the particles a crown-like appearance. The spike binds to human cells, allowing the virus to gain entry. VRC and Moderna scientists already were working on an investigational MERS vaccine targeting the spike, which provided a head start for developing a vaccine candidate to protect against COVID-19. Once the genetic information of SARS-CoV-2 became available, the scientists quickly selected a sequence to express the stabilized spike protein of the virus in the existing mRNA platform.

The Phase 1 trial is led by Lisa A. Jackson, M.D., senior investigator at KPWHRI. Study participants will receive two doses of the vaccine via intramuscular injection in the upper arm approximately 28 days apart. Each participant will be assigned to receive a 25 microgram (mcg), 100 mcg or 250 mcg dose at both vaccinations, with 15 people in each dose cohort. The first four participants will receive one injection with the low dose, and the next four participants will receive the 100 mcg dose. Investigators will review safety data before vaccinating the remaining participants in the 25 and 100 mcg dose groups and before participants receive their second vaccinations. Another safety review will be done before participants are enrolled in the 250 mcg cohort.

Participants will be asked to return to the clinic for follow-up visits between vaccinations and for additional visits across the span of a year after the second shot. Clinicians will monitor participants for common vaccination symptoms, such as soreness at the injection site or fever as well as any other medical issues. A protocol team will meet regularly to review safety data, and a safety monitoring committee will also periodically review trial data and advise NIAID. Participants also will be asked to provide blood samples at specified time points, which investigators will test in the laboratory to detect and measure the immune response to the experimental vaccine.

“This work is critical to national efforts to respond to the threat of this emerging virus,” Dr. Jackson said. “We are prepared to conduct this important trial because of our experience as an NIH clinical trials center since 2007.”

Adults in the Seattle area who are interested in joining this study should visit https://corona.kpwashingtonresearch.org/ (https://corona.kpwashingtonresearch.org/) . For more information about the study, visit ClinicalTrials.gov and search identifier NCT04283461 (https://clinicaltrials.gov/ct2/show/NCT04283461) .

Contact

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Questions & Answers

COVID-19 Investigational Vaccine Clinical Trial Launch

Who is conducting the study, and where is it being conducted?

The study is being funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health, and conducted at the Kaiser Permanente Washington Health Research Institute (KPWHRI) in Seattle. KPWHRI is part of NIAID's Infectious Disease Clinical Research Consortium (IDCRC), a clinical trials network that encompasses the Institute's long-standing Vaccine and Treatment Evaluation Units (VTEUs). Lisa A. Jackson, M.D., senior investigator at the Kaiser Institute in Seattle, will lead the study. The IDCRC was designed to respond to public health emergencies by rapidly testing candidate vaccines, diagnostics, therapeutics and other interventions in clinical trials.

Can you describe the experimental vaccine that is being tested?

The investigational vaccine, called mRNA-1273, was developed by scientists at NIAID's Vaccine Research Center in collaboration with the biotechnology company Moderna, Inc., based in Cambridge, Massachusetts. The Coalition for the Epidemic Preparedness Innovations (CEPI) supported the clinical manufacturing of the experimental vaccine for this clinical trial.

The experimental vaccine was developed using a genetic platform called mRNA (messenger RNA), which directs the body's cells to express a virus protein that, hopefully, will elicit a robust immune response. The mRNA-1273 vaccine has been tested in animal models and has demonstrated some protective ability.

How were scientists able to develop the experimental vaccine so quickly?

Prior to the COVID-19 outbreak, NIAID and Moderna scientists had been working together on an investigational vaccine to protect against Middle East respiratory syndrome (MERS), another type of coronavirus. Once the genetic sequence information for the novel SARS-CoV-2 virus became available, the scientists were able to apply that to the existing mRNA platform to create the investigational mRNA-1273 vaccine.

Describe the study design.

It is a Phase 1 clinical trial designed to evaluate different doses of the investigational mRNA-1273 vaccine for safety and their ability to induce an immune response in study volunteers. A Phase 1 study is the first step in testing an experimental vaccine in humans to evaluate its potential benefit.

The study is expected to enroll 45 healthy adult volunteers ages 18 to 55 years of age. Study participants will receive two doses of the experimental vaccine via intramuscular injection in the upper arm 28 days apart. Each participant will be assigned to receive a 25 microgram (mcg), 100 mcg or 250 mcg dose at both vaccinations, with 15 participants in each dose cohort. The first four participants will receive one injection with the low dose, and the next four participants will receive the 100 mcg dose. Investigators will review safety data before vaccinating the remaining participants in the 25 and 100 mcg dose groups and before participants receive their second vaccinations. Another safety review will be conducted before participants are enrolled in the 250 mcg cohort.

Participants will be asked to return to the study clinic for follow-up visits between vaccinations and for additional visits over a year after the second vaccination. Participants will also be asked to provide blood samples at specified times throughout the trial, which scientists will test to detect and measure the immune response to the experimental vaccine.

When will study results be available?

If the clinical trial enrolls participants as planned, researchers hope to have initial data from the clinical trial within three months.

If the study data is favorable, would the mRNA-1273 be made available to the public to protect against the COVID-19 outbreak?

If the investigational vaccine shows promise, the next step will involve larger studies enrolling hundreds to thousands of people to better understand the vaccine candidate's safety and immunogenicity, as well as to see if the experimental vaccine can protect people from infection with the virus that causes COVID-19. It is important to note that a COVID-19 vaccine will not be widely available to the public for at least a year and likely longer. Clinical testing to establish a vaccine's safety and efficacy takes time.

Seattle, which is where the study is being conducted, has had confirmed cases of COVID-19. How can you be sure that study participants have not been exposed to or infected with the SARS-CoV-2 virus?

The Seattle site was chosen before the U.S. had identified any cases, and experts could not predict if and where community transmission would occur in the United States. Importantly, study volunteers will be screened for any indication of illness and will not be enrolled in the study if they have active infection, including any signs or symptoms of COVID-19 or any known recent exposure to COVID-19. Also, participants will be enrolled gradually, starting with the low dose (25 mcg), and will be monitored closely for safety concerns. The first four participants will receive one injection with the low dose, and the next four participants will receive the 100 mcg dose.

Investigations will review safety data before vaccinating the remaining participants in the 25 and 100 mcg dose groups and before participants receive their second vaccinations. Another safety review will be done before participants are enrolled in the 250 mcg cohort. In addition, participants will be counseled about how to prevent spread of and avoid infection with SARS-CoV-2 as part of the study procedures.

How will the safety of the study participants be monitored?

Clinical staff will monitor study participants for common vaccination symptoms, such as soreness at the injection site or fever, as well as any other medical issues. A protocol team will meet regularly to review safety data, and a safety monitoring committee will also periodically review trial data and advise NIAID.

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