NIH Launches Study of Extra COVID-19 Vaccine Dose in People With Autoimmune Disease

Trial also will test pausing immunosuppressive medication to improve antibody response.

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The National Institutes of Health (NIH) has begun a clinical trial to assess the antibody response to an extra dose of an authorized or approved COVID-19 vaccine in people with autoimmune disease who did not respond to an original COVID-19 vaccine regimen. The trial also will investigate whether pausing immunosuppressive therapy for autoimmune disease improves the antibody response to an extra dose of a COVID-19 vaccine in this population.

The Phase 2 trial is sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH, and is being conducted by the NIAID-funded Autoimmunity Centers of Excellence.

“Many people who have an autoimmune disease that requires immunosuppressive therapy have had a poor immune response to the authorized and approved COVID-19 vaccines, placing these individuals at high risk for the disease,” said NIAID Director Anthony S. Fauci, MD. “We are determined to find ways to elicit a protective immune response to the vaccines in this population. This new study is an important step in that direction.”

An estimated 8% of Americans have an autoimmune disease, including a disproportionate number of people in the minority communities most severely impacted by COVID-19. Researchers have reported higher rates of severe COVID-19 and death in people with autoimmune disease than in the general population. It is unclear whether this is attributable to the autoimmune disease, the immunosuppressive medications taken to treat it, or both.

The results of recent studies indicate that giving an extra dose of an authorized COVID-19 vaccine to solid organ transplant recipients, who must take immunosuppressive medications, can improve the immune response to the vaccine in many of these individuals. A NIAID study is underway to investigate this further. The recent findings in solid organ transplant recipients also suggest that an extra dose of a COVID-19 vaccine may help some people with autoimmune disease who take certain immunosuppressive medications.

The Food and Drug Administration recently amended the emergency use authorizations for the Pfizer-BioNTech and Moderna COVID-19 vaccines to allow the administration of an additional dose to solid organ transplant recipients and other people who have an equivalent level of immunocompromise.

The new NIAID trial, called COVID-19 Booster Vaccine in Autoimmune Disease Non-Responders, initially will include people with one of five autoimmune diseases: multiple sclerosis, pemphigus, rheumatoid arthritis, systemic lupus erythematosus or systemic sclerosis. The immunosuppressive therapies commonly taken by people with these diseases have been associated with poor immune responses to vaccines.

The study team will enroll approximately 600 participants ages 18 years and older at 15 to 20 sites nationwide. Participants must have had a negative or suboptimal antibody response to two doses of the Moderna COVID-19 vaccine, two doses of the Pfizer-BioNTech COVID-19 vaccine, or one dose of the Johnson & Johnson COVID-19 vaccine, all received prior to enrollment. Participants also must be taking one of three immunosuppressive therapies: mycophenolate mofetil (MMF) or mycophenolic acid (MPA); methotrexate (MTX); or B cell- depleting drugs.

All participants will receive an extra dose of the same COVID-19 vaccine as they received originally. Then those participants who are taking MMF/MPA or MTX will be assigned at random either to continue taking their immunosuppressive medication without alteration or to pause taking their medication for a short period before and after receiving the extra vaccine dose. The main goal of the study is to determine the proportion of participants who have a significantly better antibody response four weeks after receiving the extra vaccine dose than they did after their original vaccinations.

Study participants will be followed for a total of 13 months. Preliminary results are expected in November 2021.

The COVID-19 Booster Vaccine in Autoimmune Disease Non-Responders trial is being led by Judith James, M.D., Ph.D., Meggan Mackay, M.D., M.S., Dinesh Khanna, M.B.B.S., M.Sc., and Amit Bar-Or, M.D., F.R.C.P.C. Dr. James is vice president of clinical affairs and program chair of the Arthritis & Clinical Immunology research program at the Oklahoma Medical Research Foundation in Oklahoma City. Dr. Mackay is a professor in the Institute of Molecular Medicine at the Feinstein Institutes for Medical Research in Manhasset, New York. Dr. Khanna is the Frederick G.L. Huetwell professor of rheumatology and the director of the scleroderma program in the department of internal medicine at University of Michigan in Ann Arbor. Dr. Bar-Or is the director of the Center for Neuroinflammation and Neurotherapeutics, chief of the multiple sclerosis division, and the Melissa and Paul Anderson President's Distinguished Professor at the University of Pennsylvania in Philadelphia.

Additional information about the COVID-19 Booster Vaccine in Autoimmune Disease Non-Responders trial, including the locations of study sites, is available in ClinicalTrials.gov under study identifier NCT05000216.

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