Trial Tests Strategy to Augment COVID-19 Vaccine Response in Transplant Recipients

Organ transplant recipients take immunosuppressive drugs that impair immune response to pathogens and vaccines.

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A study has begun to assess the antibody response to an additional dose of a COVID-19 mRNA vaccine in kidney and liver transplant recipients, either alone or with a concurrent reduction in immunosuppressive medication. The clinical trial will enroll people for whom two to four doses of a COVID-19 mRNA vaccine did not elicit a detectable antibody response.

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, is sponsoring and funding the Phase 2 trial, called COVID Protection After Transplant–Immunosuppression Reduction, or CPAT-ISR.

“Eliciting a protective immune response to COVID-19 vaccines in some organ transplant recipients continues to be a challenge,” said NIAID Director Anthony S. Fauci, MD. “We are concerned about protecting everyone from COVID-19 and therefore continue to develop and test new approaches to make vaccination effective for all organ transplant recipients.”

Organ transplant recipients must take lifelong immunosuppressive therapy to prevent organ rejection, and this therapy blunts their immune responses to pathogens and vaccines. Research has shown that many organ transplant recipients do not develop antibodies against SARS-CoV-2, the virus that causes COVID-19, after receiving a primary COVID-19 vaccine regimen. Even after receiving a third dose of a COVID-19 mRNA vaccine, many transplant recipients still fail to produce an antibody response. Those who do develop antibodies tend to have much weaker responses than immunocompetent people. The lack of robust antibody responses, along with a high prevalence of risk factors such as obesity and diabetes, leaves kidney and liver transplant recipients at high risk for SARS-CoV-2 infection and severe COVID-19.

The purpose of the new study is to determine if temporarily reducing immunosuppressive medication taken during the days before and after an additional dose of an mRNA COVID-19 vaccine safely allows for better antibody responses to vaccination in kidney and liver transplant recipients. Research has shown that pausing immunosuppressive medication in people with

autoimmune disease can safely improve their antibody responses to vaccinations for both COVID-19 and influenza, suggesting that this approach might also work for some transplant recipients.

The new trial builds on NIAID's CPAT pilot study, which is assessing the antibody response to a third dose of a COVID-19 mRNA vaccine in kidney transplant recipients. Dorry L. Segev, MD, PhD, leads both trials. Dr. Segev is the associate vice chair for research and the Marjory K. and Thomas Pozefsky professor of surgery and epidemiology at Johns Hopkins University in Baltimore.

The CPAT-ISR trial will take place at approximately 15 transplant centers across the United States. The study team will enroll up to 400 adults ages 18 years or older who received a kidney or liver transplant a year or more prior to enrollment. All participants will have received two to four doses of either the Moderna COVID-19 vaccine or the Pfizer-BioNTech COVID-19 vaccine at least 30 days before enrollment and will have a negative or indeterminate antibody response 30 days or more after the most recent dose. Participants must be taking one of two specific tacrolimus-based immunosuppressive medication regimens and have no recent transplant rejection or change in immunosuppression.

The study team will assign participants at random to one of two groups. One group will receive an additional dose of a COVID-19 mRNA vaccine with no further intervention. The other group will take a reduced dose of their immunosuppressive therapy for five days before and two weeks after receiving an additional dose of a COVID-19 mRNA vaccine. Investigators will measure each participant's antibody response to vaccination 30 days after the additional vaccine dose. The goal is to determine the proportion of participants who achieve a predefined antibody response at the 30-day mark. The study team will follow participants for one year after enrollment.

More information about the trial, including study site locations and contacts, is available at ClinicalTrials.gov under study identifier NCT05077254.

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