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EDITORIAL

Natera study of kidney transplant beneficiaries; immune resonses to the COVID-19 vaccine

While the data from Johns Hopkins is helpful, there is still a data gap in transplantation to understand vaccine response in kidney recipients. The Hopkins study showed that immunosuppressed SOT patients appear not to mount a normal immune response. “From what we know about the anti-rejection drugs these patients are taking, we expect to see a blunted response to the vaccine,” said Phil Gauthier, MD, transplant nephrologist and Natera’s Medical Director of Organ Health. “We may see less durability.” The Natera study hopes to find answers to these three unanswered questions:

- **What is the time course** of the induction of immune response to the vaccine by kidney transplant recipients?
- **What are the longevity and durability** of any immune response to the vaccine from kidney transplant recipients?
- **What does the Prospera transplant assessment test** show from vaccination through six months-post COVID-19 vaccination?

Determining answers to these questions allows clinicians to understand the vaccine’s effects and effectiveness on kidney transplant patients’ immunity, and the degree to which the allograft is impacted by the vaccination, if at all.

Study details

Three sites, Columbia University Medical Center, Yale New Haven Health, and University of Pennsylvania Health System, will each enroll 100 patients. The study will monitor patients immediately prior to their first vaccine, during the vaccination process for one or two doses (two for Moderna and Pfizer, and one for J&J), and six months out. Investigators will collect data on how quickly the patients form antibodies and to what magnitude.

Enrollment should be completed within six to nine months. The study will track which patients receive doses from which manufacturer, but the study will not control for that. “If possible, we could do a sub-analysis or cohort analysis if we get enough enrolled from all three manufacturers,” said Phil Gauthier, MD, transplant nephrologist and Natera’s medical director.

This will be a prospective non-controlled study. Investigators will compare the data with the greater population receiving the vaccines, using observational data potentially from the manufacturers’ reports. Data from vaccinated patients can also be compared to observational data from transplant patients who did not receive the vaccine.

As part of the study, Prospera will be used to monitor the allograft. Since vaccines rely on activation of the immune system, there is a question of whether the vaccine will put the allograft at risk. Prospera will show whether the transplanted kidney/s remain stable during the immunization process and antibody development. “If there is an early warning signal that they are at risk, we can better manage those patients moving forward,” said Gauthier.

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