

UW-Madison: Program launches first-in-US cell-therapy trial for kidney transplant patients

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MADISON, Wis. – For the first time in the United States, a research team will test a personalized cell therapy to treat a common and serious complication facing kidney transplant patients.

The UW Program for Advanced Cell Therapy (PACT) will study a cutting-edge therapy to treat a viral infection faced by around 30 to 40 percent of kidney and/or pancreas transplant recipients.

The study will deploy virus-specific white blood cells to treat severe cytomegalovirus (CMV) infection after kidney transplantation.

The Federal Drug Administration-approved trial will begin enrolling 20 adult kidney-transplant recipients, according to Dr. Arjang Djamali, professor of medicine and surgery at the UW School of Medicine and Public Health, and UW Health nephrology division chief.

Kidney transplant is the most common type of transplant in the United States, according to the U.S. Department of Health and Human Services, with about 22,000 (including combined kidney and pancreas procedures) in 2018.

UW Health is the largest kidney and pancreas transplant program in the state, performing a majority of Wisconsin's kidney and kidney-pancreas combined transplants with 315 in 2018.

"The profile of our program will allow ample trial participants," Djamali said. "We look forward to discovering if this innovative treatment strategy is safe and

effective for this unmet need.”

Nearly one in three children is infected with CMV by age 5, according to the Centers for Disease Control and Prevention. While it can cause fever, sore throat, fatigue and swollen glands, in healthy people with stable immune systems the virus is usually kept in check and doesn’t cause any symptoms. But, following kidney transplant, the patient’s immune system is suppressed and there is nothing to stop the virus from spreading in the body.

In such patients, the infection can be fatal, and some anti-viral treatments have serious side effects, such as reducing blood counts and kidney function. Additionally, viruses can develop resistance to antiviral drugs.

These factors make PACT’s new approach a potentially safe, effective treatment to stop this virus, said Dr. Jacques Galipeau, PACT director.

“The use of living cells collected from relatives with intact immunity to cure viral complications of transplantation is an entirely new therapy for a vexing problem,” he said.

The clinical trial’s procedure is to extract white blood cells from a parent or sibling with good anti-viral immunity and manipulate the cells so they are effective in attacking and destroying the virus.

This manipulation will be conducted in the program’s state-of-the-art manufacturing facility inside University Hospital in Madison. The cells will then be infused back into the patient. The entire process can be completed in about 14 hours.

Considering the nature of this viral infection, it is critical to have a manufacturing process that is robust, reproducible and has a quick turn-around time, Galipeau said.

This type of therapy is being attempted only at a few elite academic medical centers around the United States. UW Health and the UW School of Medicine and Public Health are at the forefront of the cell-therapy field, he said.

“Our vision is to bring to Wisconsin the best cutting-edge cellular technologies available worldwide, and develop our own, as well to treat catastrophic health problems for which no cure exists,” he said.

For more on the trial, please visit, clinicaltrials.gov.

To learn more about the Program for Advanced Cell Therapy, please visit: pact.wisc.edu.