UW Health: UW Program for Advanced Cell Therapy launches first clinical trial

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Cytomegalovirus study places program in rare company

MADISON, Wis. – For the first time in Wisconsin, a research team will test a personalized cell therapy to treat a common and serious complication in bone-marrow transplant patients.

The UW Program for Advanced Cell Therapy (PACT) will conduct a study to examine a cutting-edge therapy to treat a viral infection faced by up to 50 percent of bone-marrow transplant recipients.

The program's first study will deploy virus-specific white blood cells to treat lethal cytomegalovirus (CMV) reactivation that can occur after a bone-marrow transplant.

The Food and Drug Administration-approved trial will begin enrolling adult and pediatric patients immediately through a partnership with UW Health, according to Dr. Inga Hofmann, PACT medical director and principal investigator on the trial.

"While some European countries might offer this type of treatment as standard care, it is considered experimental in the United States. We believe it is critically important to assess these types of cellular therapies through a clinical trial to carefully monitor safety and efficacy," she said. "It also allows us to continue to learn how we can improve such treatments and how they work."

Nearly one in three children are already infected with the 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 bone-marrow 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 antiviral 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, according to Dr. Nirupama Pike, PACT director of cell manufacturing. 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, Pike said.

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.

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, according to Galipeau.

"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.