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Diabetes Research Institute Successfully Transplants First Patient In Pilot BioHub Trial

Study Evaluates Alternative Site for Islet Transplantation

PR Newswire

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MIAMI, Aug. 26, 2015 /PRNewswire-USNewswire/ -- The Diabetes Research Institute (DRI), a Center of Excellence at the University of Miami Miller School of Medicine, announced today that the first patient in its clinical trial to test for the first time a novel transplant technique for insulin-producing cells was successfully completed. This FDA approved Phase I/II study builds upon decades of progress in clinical islet transplantation and is an important first step toward the development of the DRI BioHub, a bioengineered mini organ that will mimic the native pancreas to restore natural insulin production in people with type 1 diabetes.



"This was the first transplant of islets on the surface of the omentum, a highly vascularized tissue covering abdominal organs, using a biologic, fully re-absorbable scaffold technique. The site is easily accessed by minimally invasive surgery, and more importantly, has the same blood supply and drainage characteristics of the pancreas – where islets are originally found before they are destroyed in type 1 diabetes," explains Camillo Ricordi, MD, director of the DRI and the Stacy Joy Goodman Professor of Surgery, Distinguished Professor of Medicine, Professor of Biomedical Engineering, Microbiology and Immunology at the University of Miami Miller School. Dr. Ricordi also serves as director of the DRI's Cell Transplant Program. "This is the first tissue engineered islet transplant using a 'biodegradable scaffold' implanted on the surface of the omentum, to minimize the inflammatory reaction that is normally observed when islets are implanted in the liver or in other sites with immediate contact to the blood. Avoidance of inflammation has been shown to be important to minimize harm to the newly transplanted islets, and we are all very excited about the potential of this new clinical trial."

The biodegradable scaffold, one of the platforms for a DRI BioHub, is a combination of a patient's own blood plasma and thrombin, a commonly used, clinical-grade enzyme. When combined, these substances create a gel-like material that sticks to the omentum and holds the islets in place. The omentum is then folded over around the biodegradable scaffold mixture. Over time, the body will absorb the gel, leaving the islets intact, while new blood vessels are formed to provide critical oxygen and other nutrients that support the cells' survival. This pilot trial will include the immunosuppressive regimen currently used for clinical islet transplantation studies and will be limited to a small group of participants.

"The objective of this first trial is to show that these cells can function in this new transplant site, but demonstrating safety is paramount to all of us; safety first and then effectiveness," adds Rodolfo Alejandro, MD, Professor of Medicine and director of the DRI Clinical Cell Transplant Program. "We hope that in the omentum, which is quite rich in blood vessels, vascularization is accelerated allowing more islets to survive and engraft, and that we can show that this site is both a safe and viable alternative as a transplant site on which to further the DRI BioHub projects."

In type 1 diabetes, the insulin-producing islets cells of the pancreas have been mistakenly destroyed by the immune system, requiring patients to manage their blood sugar levels through a daily regimen of insulin therapy. Islet transplantation has allowed some patients to live without the need for insulin injections after receiving a transplant of donor cells. Some patients who have received islet transplants at the DRI have been insulin independent for more than a decade, as DRI researchers have published.

Currently, islet cells are infused into the liver, but many of the cells do not survive in that environment. "The liver is a very simple site to access, but we have known for years that it's not the ideal site. And the liver will not accommodate a device for housing the islets," explained Dr. Alejandro.

"We have to show initially that this transplant can function and be equivalent to the liver as a site of implantation," explains Dr. Ricordi. "We will then add all the other components that will favor new blood vessel development, oxygen generation, cell protection and other agents that will allow us to reduce and eventually eliminate systemic immunosuppression, which is our ultimate goal for a biological cure."

To learn more about the DRI's clinical trial and the transplant procedure, please visit <http://www.DiabetesResearch.org/DRItv>

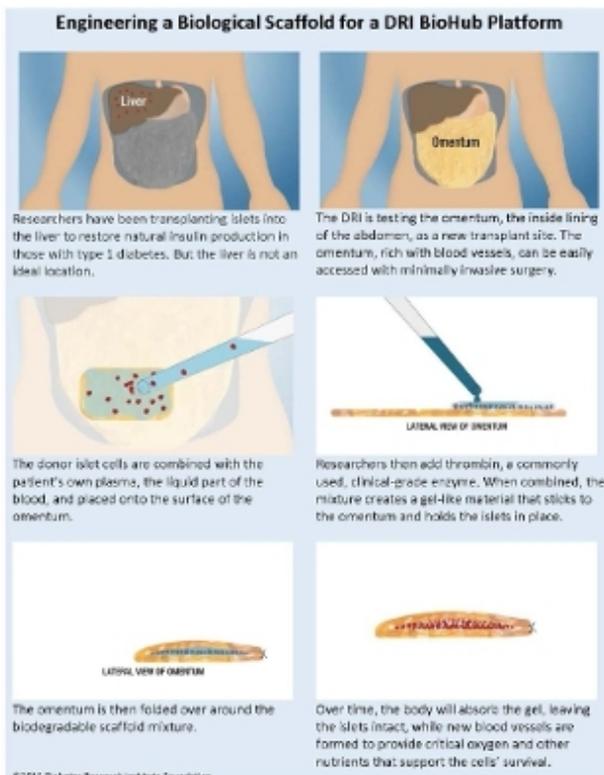
The research projects that comprise the DRI BioHub receive philanthropic support from the Diabetes Research Institute Foundation. Funding for the DRI BioHub is also provided by other sources, including JDRF, The Leona M. and Harry B. Helmsley Charitable Trust, National Institutes of Health (NIH), NIH Small Business Innovation Research (SBIR), University of Miami, pharmaceutical companies, and additional corporate and philanthropic partners. For more information on the development of the BioHub, visit www.DiabetesResearch.org/BioHub

About the Diabetes Research Institute

The Diabetes Research Institute at the University of Miami Miller School of Medicine leads the world in cure-focused research. As the largest and most comprehensive research center dedicated to curing diabetes, the DRI is aggressively working to develop a biological cure by restoring natural insulin production and normalizing blood sugar levels without imposing other risks. Researchers have already shown that transplanted islet cells allow patients to live without the need for insulin therapy. The DRI is now building upon these promising outcomes by developing the DRI BioHub and is testing various BioHub platforms in preclinical and clinical studies. For more information, please visit DiabetesResearch.org or call 800-321-3437. You can tweet DRI at @Diabetes_DRI.

Acknowledgements

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