

Allison Nimlos | Aug 19, 2014



For most of us with diabetes, diabetes cure research can feel like it's moving at a glacial pace. If you're a mouse, it's probably pretty exciting, considering researchers are discovering new ways to cure you almost every day. But what progress is being made in curing this disease? Is anyone moving beyond the lab rats and into people living with diabetes? The good news is yes, and there are a lot of people working on finding a cure, and many of them have started or will be starting clinical research in humans soon.

There are many barriers and obstacles facing researchers. Understanding how the human body works and the mechanisms behind how diabetes happens have been a continual learning process for scientists. On top of that, researchers often struggle to fund their research or get their clinical trials approved by the Food and Drug Administration. Luckily, there are many researchers in the United States and around the world who are committed to finding a cure for diabetes.

Clinical Islet Transplantation Consortium

What They're Working On: In 2005, The Clinical Islet Transplantation Consortium was created by the National Institutes of Health. It consists of 13 universities and medical centers around the world, including the University of Pennsylvania, Massachusetts General Hospital, UC San Francisco, and University of Illinois at Chicago.

The CIT Consortium has several goals: improving islet cell transplantation techniques; reducing the complications of the procedure; reducing the effects of immunosuppression; achieving better long-term success with islet cell transplantation; better ways to prevent immune rejection.

What's New: The multi-year, multi-center Phase III clinical trial recently finished in the spring, but the final results have not yet been made public. The trial itself was presented at the International Society for Cellular Therapy in April and was awarded Best Presentation, but the researchers could not discuss primary endpoints. Results won't be discussed until the trial is published in a peer-reviewed journal, which hopefully will happen before the end of 2014.

Diabetes Research Institute

What They're Working On: In 2013, the Diabetes Research Institute announced they are developing the BioHub, described as a "mini organ" that would provide the insulin-producing cells with the spacing, support, oxygen and nutrients they need to survive. The BioHub would also protect transplanted islet cells from the autoimmune attack without the need for anti-rejection drugs. Up until now, the liver was the location of choice for transplanting islet cells, but the DRI is investigating alternative sites that might provide better absorption for insulin.

What's New: The Food and Drug Administration recently approved a plan to launch a pilot clinical study to test islets transplanted into a "biodegradable scaffold," one of the platforms considered for a DRI BioHub. The pilot trial will start this year. The trial will also compare the omentum - an apron-like lining inside the abdomen - to the portal vein in the liver to see which is the best for islet cells.

The DRI is also in the early stages of another pilot trial looking at re-educating the immune system so that it wouldn't destroy a person's islet cells. This would allow for the transplantation of islet cells without anti-rejection drugs and would prevent a recurrence of type 1 diabetes.

Faustman Lab

What They're Working On: Dr. Denise Faustman and her team are studying the use of Bacillus Calmette-Guerin (BCG) a drug currently used as a vaccine for tuberculosis and also a treatment for bladder cancer. In their Phase 1 human clinical study, BCG was shown to eliminate the T-cells responsible for destroying the insulin-producing beta cells and temporarily restored the insulin production.

What's New: The Faustman Lab is currently finalizing the design for their Phase II clinical trial, which will be done in humans, as well fundraising for the trial. They currently need to raise an additional \$7 million. Researchers hope to identify the proper dosing of BCG to eliminate the defective T-cells and permanently restore insulin production.

ViaCyte

What They're Working On: ViaCyte has created the VC-01 combination product, an integration of two of its products. The first, PEC-01 cells, are proprietary pancreatic cells derived from human embryonic stem cell lines. The second, the Encaptra drug delivery system, is a small device that protects the PEC-01 cells from the immune system.

Once the PEC-01 pancreatic cells mature into insulin, amylin, and glucagon-producing cells, the Encaptra device allows those hormones to flow into the body in response to changes in blood sugar while preventing the immune system from destroying the foreign cells.

What's New: Viacyte finished preclinical proof-of-concept studies in mice showing that the device is successful in managing blood sugar. ViaCyte is now working on getting approval from the FDA to conduct human clinical trials. They hope to start human trials in the next two years. In February 2014, JDRF announced it will fund \$7 million to ViaCyte's human clinical trial once it is approved by the FDA.

Orgenesis

What They're Working On: Orgenesis is a Belgian company working to restore insulin production through a process called cellular trans-differentiation. This novel approach converts a patient's own liver cells into insulin-producing islet cells. While it eliminates the issue for anti-rejection medication, it does not address the patients own islet-cell attacking immune system.

What's New: Orgenesis recently secured \$1.5 million in funding which they hope will allow them to pursue human clinical trials sooner.

Living Cell Technologies

What They're Working On: Living Cell Technologies (LCT) developed Diabecell, an encapsulation device that houses pig islet cells, rather than human islet cells. This device was tested in humans in Argentina, New Zealand and Russia.

What's New: In November 2013, results from a Phase I/IIa clinical trial was released. A small sample of eight patients was implanted with the Diabecell device, and the results hypoglycemic events dropped and A1C decreased in almost all of the patients, but not all patients achieved an A1C under 7 percent. Inquiries into the latest news from Living Cell Technologies were unanswered at this time. We can only hope that their work will continue.

- See more at: <http://diabeteshealth.com/read/2014/08/19/8355/-researching-the-cure-beyond-the-mouse/#sthash.BCUe8lLv.dpuf>