

Is **ISLET CELL** Transplantation an Option for You?

Do you or someone you know have Brittle Diabetes or Hypoglycemia Unawareness?

Are you aware islet cell transplantation clinical trials are presently underway to treat individuals with diabetes who suffer from brittle diabetes or hypoglycemic unawareness? Islet cell transplantation, when successful, has been shown to restore insulin independence and to protect from severe hypoglycemia in people with type 1 diabetes. Since 2000, more than 400 people with type 1 diabetes have had an islet cell transplant in North America.

The purpose of the current transplant clinical trials is to help make islet cell transplantation a safe and effective treatment for those with type 1 diabetes. It is exciting to note the significantly improved outcomes from the islet cell transplant clinical trials as expertise and knowledge are gained from the early participants; however, more studies are needed before the procedure can be made available to everyone.

To advance these studies the National Institutes of Health has established the Collaborative Islet Transplant Registry. The mission of the Registry is to expedite progress and promote safety through the collection, analysis, and communication of comprehensive and current data on all islet transplants performed in North America, as well as some European and Australian centers.

As is the case with all forms of transplantation, an islet transplant may not be suitable for everyone.

Who may benefit?

Individuals who may qualify for islet cell transplantation either

- have severe hypoglycemia unawareness **OR**
- have had a kidney transplant and are taking immunosuppressant drugs.

Eligibility Criteria for clinical trial:

- Type 1 diabetes for more than five years
- Age 18 to 65
- Wide swings of blood sugar levels
- Blood glucose lability
- Check blood sugar at least three times per day
- Administer at least three insulin injections per day, or use an insulin pump
- Have one or more complications from diabetes
- Have seen a diabetes care team at least three times in the last year

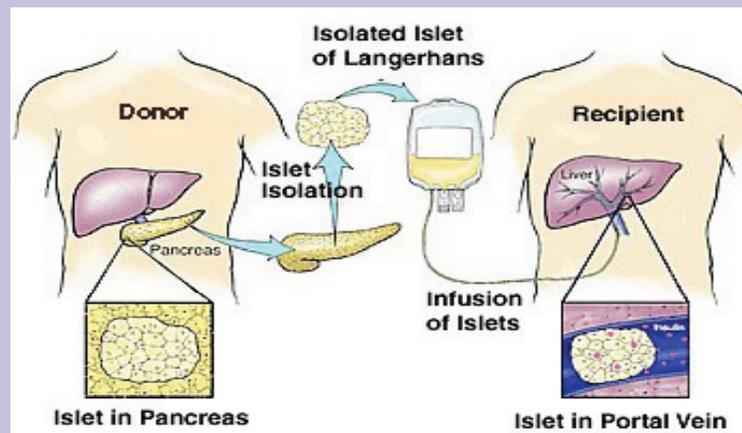
If a patient meets these criteria, further screening will be necessary to determine eligibility.

Since 1999 thirty-two medical institutions in the United States and Canada have had islet transplantation programs. Currently, fourteen centers have active clinical trials whose purpose is:

- to determine if insulin independence and/or improvement in glycemic control can be achieved;
- to assess the long-term function of successful islet transplants;
- to determine the risks of associated immunosuppressive medication
- to determine if the natural history of diabetes complications is altered.

Each center publishes the results of their studies and makes them available for review.

Figure 1
Islet Cell
Transplantation
Procedure



Islet Cell Transplantation Procedure

So, where do the islets come from and how is an islet transplant performed?

Islets are isolated from a deceased donor's pancreas and injected into the recipient's liver via the portal vein. The transplanted islets function as they do in the pancreas and produce insulin in response to glucose found in the blood as it flows through the liver. **See Figure 1**

Recipients usually recover quickly from the procedure and are discharged from the hospital two to three days after the transplant. A second or third islet transplant is considered if the first does not stop the need for insulin injections, or if blood glucose is not well controlled.

If successful, the transplanted islets will produce enough insulin so that the transplant recipient no longer needs to take insulin. If the transplant is partially successful the recipient should experience more stable blood sugar control—requiring less insulin, with fewer low blood sugar reactions. Because improved control of blood sugar has been shown to slow the complications of diabetes, islet transplant recipients may benefit whether their transplant is fully successful or partially successful. Preliminary studies suggest that islet transplants also improve quality of life. Further studies monitoring the development and progression of diabetes complications and the quality of life in more transplant recipients — for longer durations — are needed to assess the true benefits of islet transplantation.

Risks

It is important to remember that while islet transplantation is being developed as a safe alternative to pancreas transplantation, people who participate in islet transplant trials may have more problems resulting from study participation than if they continued insulin treatment alone. Islet transplantation is an experimental treatment and, as with any experimental treatment, there is a risk that rare or previously unknown complications can occur.

There are two main types of risks associated with islet transplantation.

The first involves the risks associated with the transplant procedure itself, which include slowed breathing from the anesthesia, severe bleeding, blood clots, abnormal liver function, accidental injury to organs, infection, a decrease in blood pressure, pain, extra exposure to x-rays, allergic reaction to contrast dye and—very rarely—death.

The second involves the risks associated with the use of anti-rejection drugs—also known as immunosuppressive or immunosuppressant drugs. These drugs are used for all transplants and must be taken daily for the rest of the patient's life to prevent the body from rejecting the transplanted organ. Immunosuppressant drugs may weaken the recipient's immune system, which can lead to serious infections and cancer.

For more information

We recommend you visit these websites to learn more about islet cell transplantation trials; logon to the Clinical Islet Transplantation Registry website at www.citregistry.org, the Clinical Islet Transplantation Consortium at www.citiletstudy.org, or <http://clinicaltrials.gov/> and search for islet cell transplants.

In addition, each year the Registry provides a comprehensive overview of the cumulative data since 1999. The sixth report, published in 2009, summarizes information on 408 patients who received one or more islet cell transplants between 1999 and 2008 inclusively.

CITR Annual Reports are public and can be downloaded or requested in hard copy at www.citregistry.org.

Please also contact the DRWF helpline to ask questions and to find out more about islet cell transplantation. DRWF is here to help and assist those who are interested in this transplant procedure. Call and speak to our Certified Diabetes Educator at 1-800-941-4635.

DRWF is a strong supporter of empowering our community with the proper information about these life-changing transplants. You can also visit our website, www.diabeteswellness.net, to watch videos of personal stories from people who have received an islet cell transplant.



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www.diabeteswellness.net

Helpline Questions 1-800-941-4635 • Administrative offices 202-298-9211

An Organization for People Who Live with Diabetes Every Day.

The mission of **Diabetes Research & Wellness Foundation** (DRWF) is to help find the cure for diabetes, and until that goal is achieved, to provide the care and self-management skills needed to combat the life-threatening complications of diabetes.

Thank you for your confidence in the programs and services that the Diabetes Research & Wellness Foundation® provides to the community.

**Please designate us in the Combined Federal Campaign & United Way.
Check box #11629.**