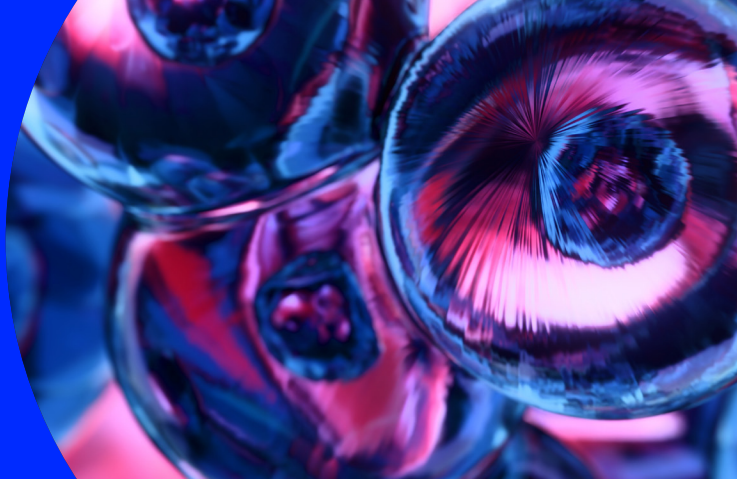




Understanding Islet Cell Therapy for T1D

Achieving recommended blood sugar levels remains challenging for many individuals with type 1 diabetes (T1D), even with modern technologies. Some people with T1D experience frequent or severe low blood-sugar episodes and struggle to reach glucose target ranges despite standard of care treatment. Severe hypoglycemia is when low blood sugar causes loss of consciousness, seizures, or requires someone else to administer emergency treatment. This is especially dangerous in people who do not have any symptoms as their blood sugar drops. These life-threatening episodes can lead to accidents, use of emergency services, and additional emotional, social, and economic burdens. Islet cell therapy may alleviate these burdens and eliminate or reduce the need for insulin therapy.

What is Islet Cell Therapy and How Does it Work?

Islet cell therapy replaces the insulin-producing cells that are destroyed by the immune system in T1D. The islet cells may be obtained from deceased organ donors or, in research studies, manufactured in a well-controlled laboratory environment. At this time, because the cells are not from the person's own body, immunosuppressive medications (anti-rejection medications) must be used to protect the cells from being attacked and rejected by the immune system. These are very similar to the medications a person would receive for an organ transplant (like a kidney or liver transplant). Taking immunosuppressive medication can have serious side effects. There is ongoing research to eliminate the need for these medications or find safer alternatives.

Potential Benefits of Islet Cell Therapy



Reduce severe, dangerous low blood-sugar episodes



Improve glucose levels (HbA1c, Time in Range)



Decrease the psychological burden of ongoing T1D management



Decrease or eliminate insulin requirements



Reduce the risk of eye, heart, and kidney complications



Improve overall well-being and quality of life

Who May Be Eligible for Currently Available Islet Cell Therapies?

Currently, access to islet cell therapies is limited to adults with T1D who experience one or more of the following: repeated episodes of severe hypoglycemia, an inability to recognize low blood sugars, an inability to reach glucose targets despite access to ongoing, quality diabetes care, those who have had a kidney transplant, or have a severe insulin allergy. The exact requirements vary according to country and whether the treatment is part of clinical care or a research trial. Having these issues does not guarantee one will be eligible to receive islet cell therapy as the risk and benefits need to be evaluated for each individual.

With your support, we are creating a movement to improve and change life with T1D, advancing breakthroughs on the way to cures.

To find out more, visit **BreakthroughT1D.org**.

Is Islet Cell Therapy a Lasting Cure for T1D?

Not yet—but Breakthrough T1D is strongly supporting research and clinical trials to make them a sustainable, long-term cure for T1D. Currently, right after donor islet cell therapy, up to 8 out of 10 people no longer need insulin. With islet transplants from a deceased donor, some patients need 2 or 3 transplants in order to stop taking insulin. Over time, fewer people stay insulin free. About 6 out of 10 people are insulin free after 1 year, 3 out of 10 after 5 years, and 1 out of 10 after 10 years. However, even if there is a need to stay on or resume insulin therapy, the islet cells may continue to prevent low blood sugar and help people reach glucose targets. People receiving this treatment currently must continue taking immunosuppressive medications to keep the administered islet cells alive and healthy.

There are many ongoing clinical trials in which islet cells are protected using new strategies. This could eliminate the need for immunosuppressive medications long-term. While these studies are very exciting, they are still very early.

The Procedure and Its Risks

Islet cell therapy is a minimally invasive procedure performed under anesthesia. The procedure may have risks such as bleeding, blood clots, or infections; it also may not work for everyone.

Monitoring on Immunosuppression

Currently, immunosuppressive medications are needed long-term after receiving islet cell therapy to protect the cells from being destroyed by the immune system. Common side effects may include low blood counts and minor symptoms like upset stomach. More serious but less common complications can include serious infections, kidney injury, or increased cancer risk.

If you are eligible for islet cell therapy, the specific immunosuppressive medications will be discussed with you by your healthcare provider. Monitoring while on immunosuppressive therapy includes regular testing of blood counts and liver and kidney function. Some medications can cause kidney injury, which can be permanent; close monitoring is needed to adjust the immunosuppressive regimen if necessary.

People taking immunosuppressive medications are also at increased risk for serious infections and may be slower to recover when ill. Before receiving islet cell therapy, an evaluation is performed for infections that could reactivate during treatment.

Your care team will provide recommendations both before and after the procedure to keep you healthy and well. This may include recommendations about vaccinations, cancer screening, what to do if you are ill or have a fever, and other important instructions.

Some immunosuppressive medications are unsafe during pregnancy; consultation with a specialist and high-risk obstetrician are essential for those considering pregnancy.

Learning if Islet Cell Therapy Is Right for You

Eligibility is determined in consultation with your healthcare team and may differ based on country and treatment setting. Not all patients with T1D qualify for islet cell transplant. The risks of T1D and insulin therapy in an individual must be weighed against the risks of the procedure and immunosuppression. Talk with your healthcare team to learn if islet cell therapy is right for you. You may be referred to a specialized center to learn more.



Visit Breakthrough T1D's clinical trials page to learn more about ongoing islet cell therapy clinical research studies.