



INFORMATION FOR ELIGIBLE PARTICIPANTS

Purpose of the Study

The purpose of this study is to evaluate the safety, tolerability, and effectiveness of an investigational islet cell infusion, called VX-880, in individuals with type 1 diabetes with severe low blood sugar (hypoglycemia) and impaired hypoglycemic awareness. The goal of this infusion is to provide replacement cells for the ones that have been lost or don't work properly in people with diabetes.

What to Expect

Before you can take part in this study, you will be asked to sign an informed consent form confirming that you have been informed about the details of the study and agree to participate. You will then need to attend screening visit(s) to complete initial tests and assessments to see if you are eligible to participate. After all necessary tests and assessments have been completed, and if you are eligible to participate, you may enter the study and may be able to receive the investigational infusion.

If you qualify, you will receive all study-related medications and procedures at no cost. You and your study doctor may choose to have some of the study visits at your home with a home health nurse, allowing for a reduced number of times that you must travel to the study site. You may also be compensated financially for your study-related time and reimbursed for travel.

About the Infusion Process

The infusion consists of a mixture of islet cells made from human embryonic stem cells. The islet cells will be delivered to participants through an infusion into a large vein that carries blood to the liver.

After the screening period, you will enter the pre-infusion period. During this period, you will be admitted to the hospital for approximately three days before the planned islet cell infusion. The study team will perform tests and procedures to make sure you are still eligible to receive the islet cell infusion. You will receive several medicines before, during, and after the infusion of the islet cells. The medicines include immunosuppressants, which prevent your body from destroying the infused islet cells, and medicines to help prevent possible side effects, blood clots, and infections. You may have a thin plastic tube called a catheter placed into a vein in your arm or neck to administer some of the medicines.

After all the required medicines have been administered and all testing has been completed, the infusion process will begin. A catheter will be inserted into your portal vein, which is a large blood vessel that carries blood to your liver. The islet cells will then be delivered slowly, over about 30–90 minutes.

At the end of the infusion, the catheter will be removed and the area where the catheter was inserted will be sealed to prevent bleeding. You will be asked to stay in the hospital after the infusion for approximately four days for safety monitoring.

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Study Participation

The infusion of islet cells will occur up to 90 days after the screening visit, but it may happen sooner. There may be a second infusion if you are enrolled in the first part of the study. The follow-up period is approximately five years following your final infusion.

Study Eligibility

Eligible participants must meet the following key criteria:

- Male or female between the ages of 18 and 65 (inclusive)
- Diagnosed with type 1 diabetes with documented severe hypoglycemia and impaired hypoglycemic awareness
- Blood type A or AB
- Do not have significant active infection or chronic infection such as hepatitis B or C, HIV, tuberculosis, invasive aspergillus, histoplasmosis, or coccidioidomycosis within the past year
- Do not have advanced complications associated with diabetes including untreated proliferative retinopathy, skin ulcers, or amputations attributable to diabetes
- Consistent use of a continuous glucose monitor (CGM) for the last three months
- Willing and able to comply with the study instructions

There are additional eligibility requirements, which the study doctor will explain to you.

FOR MORE INFORMATION ABOUT THE STUDY, PLEASE VISIT [T1DSTUDY.COM](https://www.t1dstudy.com)

