

The VX22-264-101 Study is looking for individuals living with type 1 diabetes (T1D) to participate in a study of an investigational cell-based therapy called VX-264. VX-264 consists of cells designed to produce insulin contained within devices designed to protect the cells from the immune system. These investigational devices are implanted in the space behind the muscles of the abdominal wall.

Researchers are studying the safety, tolerability, and effectiveness of VX-264 in adults with T1D and are looking to see if it could potentially reduce or eliminate the need for individuals with T1D to take insulin.

To learn more, talk to your doctor and visit 264.T1DStudy.com today.

What You Should Know about Clinical Research Studies

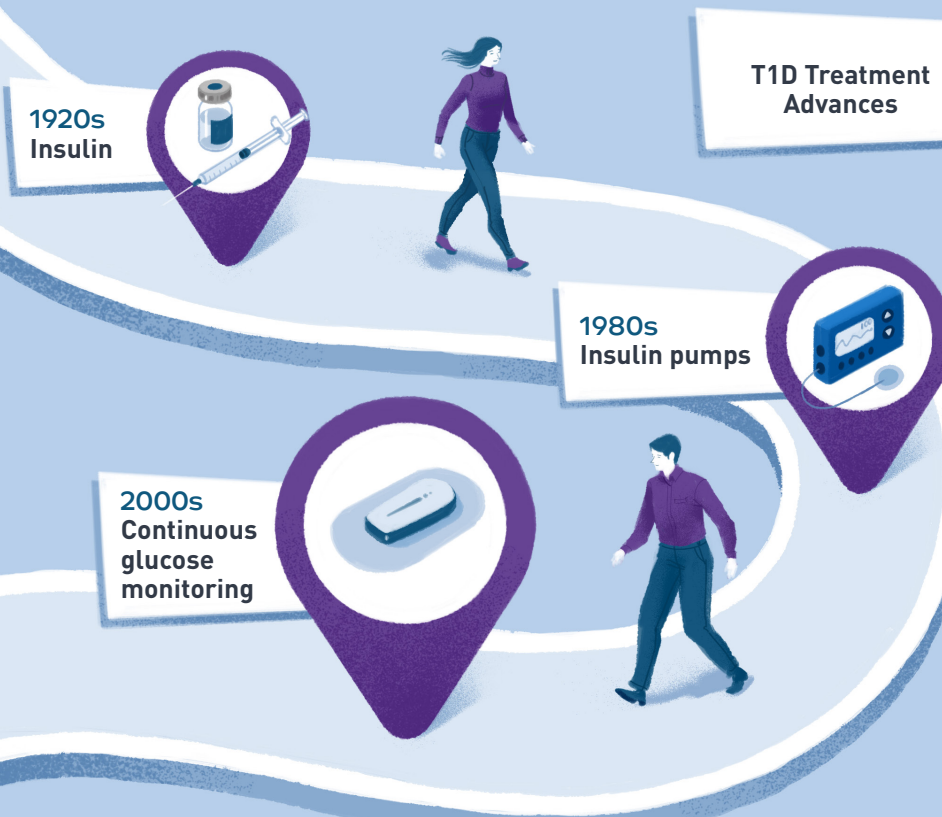
A clinical research study, sometimes called a clinical trial, is done to determine if an investigational treatment is safe and effective. We encourage patients to speak first with their physician(s) about the appropriateness of participating in research given their specific medical situation. New medical therapies are made possible by the volunteers who participate in studies. Thank you for your consideration of this important study.

Taking part in research is your choice, and you may leave a study at any time for any reason. You should consult the study doctor and staff about study-related concerns and questions you have at any time before or during the study.

Thank you for considering the VX22-264-101 Study!
To learn more, scan the QR code or visit 264.T1DStudy.com.



Type 1 Diabetes (T1D) Treatment Continues to Evolve



About the VX22-264-101 Study

The standard treatment for T1D is insulin given by multiple daily injections or a pump. However, this treatment does not always sufficiently control blood sugar levels. With current available treatments, diabetes management involves a complex balance of monitoring blood sugar levels, delivering insulin, and managing lifestyle (food, activity, stress, etc.), and becomes a constant part of life. This continued burden, despite advances in treatment, is one of the reasons why research studies like the VX22-264-101 Study are being performed to evaluate potential treatments and therapies.

VX-264 is considered investigational, which means it is not approved as a marketed product by Health Canada, the United States Food and Drug Administration (FDA), the European Medicines Agency (EMA), or any other regulatory (government) authority.

All participants in the VX22-264-101 Study will receive the investigational therapy. VX-264 is comprised of cells designed to control blood sugar levels contained within devices designed to protect these cells from the body's immune system. VX-264 is implanted in the space behind the muscles of the abdominal wall in a surgical procedure under general anesthesia. All components of VX-264 are investigational, including the containers that hold the devices prior to surgery and the specialized tools used to surgically implant the devices.



Study Design

The total length of participation in this clinical study is approximately five years and consists of the following:



Prescreening period – This period lasts up to 45 days. The purpose of the prescreening period is to determine if the potential participant is eligible to be screened for study participation. Visits during this period have the option of being conducted remotely via home health services.



Screening period – This period lasts up to 90 days. Certain tests and procedures may be done to make sure the potential participant is eligible to participate in the study.



Treatment period – During the treatment period, participants will have the investigational cell-based therapy implanted, and the study team will monitor their health. Participants will be admitted to the hospital on the day before the surgery and then will stay in the hospital for monitoring after the implant. The length of the hospital stay will depend on the study doctor's discretion but is expected to last three or four days.



Follow-up period – Participants will attend several follow-up visits to check their health after receiving the investigational cell-based therapy implant. The follow-up period will last approximately five years. Some visits during this period have the option of being conducted remotely via home health services.

Who Can Participate?

Eligible participants must:

- Be between the ages of 18 and 65 (inclusive)
- Have had insulin-treated T1D for at least five years
- Have blood type A or AB
- NOT have had prior islet cell transplant, organ transplant, or cell therapy
- NOT have advanced complications associated with diabetes, including untreated advanced diabetic retinopathy, diabetic nephropathy, skin ulcers, or amputations attributable to diabetes

There are additional eligibility requirements, which the study doctor will discuss with those interested in participating.

For more information,
talk to your doctor and
visit 264.T1DStudy.com.

