

Type I Diabetes Mellitus Clinical Trial

University of California, Irvine | UCLA-UCI Alpha Stem Cell Clinic | UCI Diabetes Center

Study Title: An Open-Label, First-In-Human, Study Evaluating the Safety, Tolerability, and Efficacy of VC-02™ Combination Product in Subjects with Type 1 Diabetes Mellitus and Hypoglycemia Unawareness

Lead Investigator: Qin Yang, MD, PhD

What is the study?

The purpose of this study is to test a possible new treatment called VC-02 for Type I Diabetes. This study will test whether the VC-02 Combination Product can be implanted and maintained with safety, tolerability, and effectiveness.

How long will my participation last?

Study participation lasts up to 2 years and involves about 18 study visits.

How can I take part in this trial?

At UC Irvine, we will enroll up to 10 adult subjects who have Type I Diabetes (T1DM) and hypoglycemia unawareness. Please note this may not be a complete list of eligibility criteria.

Main Inclusion Criteria

- Adults, ages 18-65 years of age
- Have had a diagnosis of T1DM for a minimum of 5 years
- Are on a stable insulin regimen for at least 3 months
- Have documented hypoglycemia unawareness or significant glycemic lability
- Had at least one hypoglycemic event in the past year

Main Exclusion Criteria

- Have history of islet cell (cells of the pancreas), kidney, or pancreas transplant
- Diabetic complications, including Kidney Disease (stages 3-5), kidney dysfunction, proliferative retinopathy (an eye disease in diabetic patients), nerve damage, amputations, and foot ulcers
- Had six or more severe hypoglycemic events within six months of enrollment

- Major skin conditions, certain thyroid, respiratory and heart conditions, asthma or lung disease
- Prior history of cancer

How does it work?

Patients will be screened for safety and eligibility through a review of their medical history, physical assessments, and blood tests. Eligible patients will be surgically implanted with the VC-02 Combination Product and will be evaluated for the effectiveness, safety and tolerability of VC-02 through follow-up visits over the following two years. These visits include physical assessments, blood tests, and glucose testing. Patients will also need to maintain a daily diary throughout the course of the study including insulin doses and glucose levels.

Description of the Study Product: The study product, VC-02, consists of pancreatic endoderm cells (from human embryonic stem cells), and a delivery device designed to hold the cells at the implant location. The product is about half the size of a business card and is implanted under the skin of the back, abdomen, arms, or legs.

Where is the study conducted?

At the UC Irvine Diabetes Center at Gottschalk Medical Plaza in Irvine, CA and the UC Irvine Medical Center in Orange, CA.

Will I be compensated?

Participants will receive \$40 at specified time points, up to a total of \$520 for full study participation.

For more information, please contact:

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