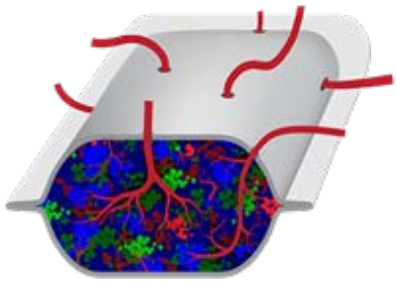
If you have Type 1 Diabetes you may be eligible to participate in a clinical trial

A Safety, Tolerability, and Efficacy Study of VC-02™ Combination Product in Subjects with Type 1 Diabetes Mellitus and Hypoglycemia Unawareness

What is this Clinical Trial about?



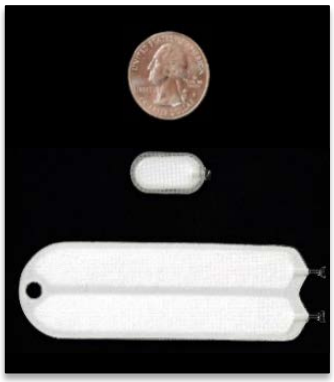
This study will determine whether PEC-Direct™, an investigational therapy, is safe to use and whether it may provide blood glucose control in a similar manner to what a "replacement pancreas" would do by producing insulin after it is surgically placed. The goal is to develop a therapy that can free patients with type 1 diabetes from long-term insulin dependence (i.e., no insulin injections or insulin pumps needed).

What is PEC-Direct (VC-02)?

The PEC-Direct (also called VC-02) Clinical Trial is evaluating a new therapy for Type 1 Diabetes which has not been approved by the US Food and Drug Administration, Health Canada, or other regulatory agencies. VC-02 consists of two parts:

1) Pancreatic beta cell precursor cells (PEC-01™), which are made from stem cells.
2) A small pouch (a medical device "unit") which is designed to hold the PEC-01 cells, and after being surgically implanted under your skin, if effective, will allow hormones including insulin to be released into your blood stream.

A surgeon will implant up to 12 units through up to 6 small incisions in your skin. Some will be the larger (bottom) unit in the figure below, which is about half the size of a business card. The remaining units will be the smaller units, which are about the size of a dime. After surgical implant, the precursor cells gradually mature into endocrine cells which secrete insulin, glucagon, and other hormones in a regulated manner to control blood glucose levels.



What will happen in this study?

- The study will last approximately 2 years. Volunteers will come to the study clinic for about 18 visits over the 2 years. Units will be surgically removed at different time points during the study to evaluate how the therapy is doing.
- The study doctor will prescribe immunosuppression medication to help the cells thrive and to prevent your body's immune system from rejecting the implanted VC-02 units. It is important you carefully follow immunosuppression instructions given by the Study Doctor.
- You will be asked to provide daily records of your insulin usage and details of any hypoglycemic event that you experience. You will wear a continuous glucose monitor, and at various time points your blood will be drawn for laboratory tests.

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Who can sign up for this study?

Men and non-pregnant women of non-childbearing potential, 18-65 years old, currently on a steady diabetic treatment regimen may be eligible to participate in the study.

Can I receive VC-02 combination product without joining the study?

No, the VC-02 combination product is currently for investigational use only and not approved for use outside of the clinical trial by the United States Food and Drug Administration, Health Canada, or any other regulatory agency.

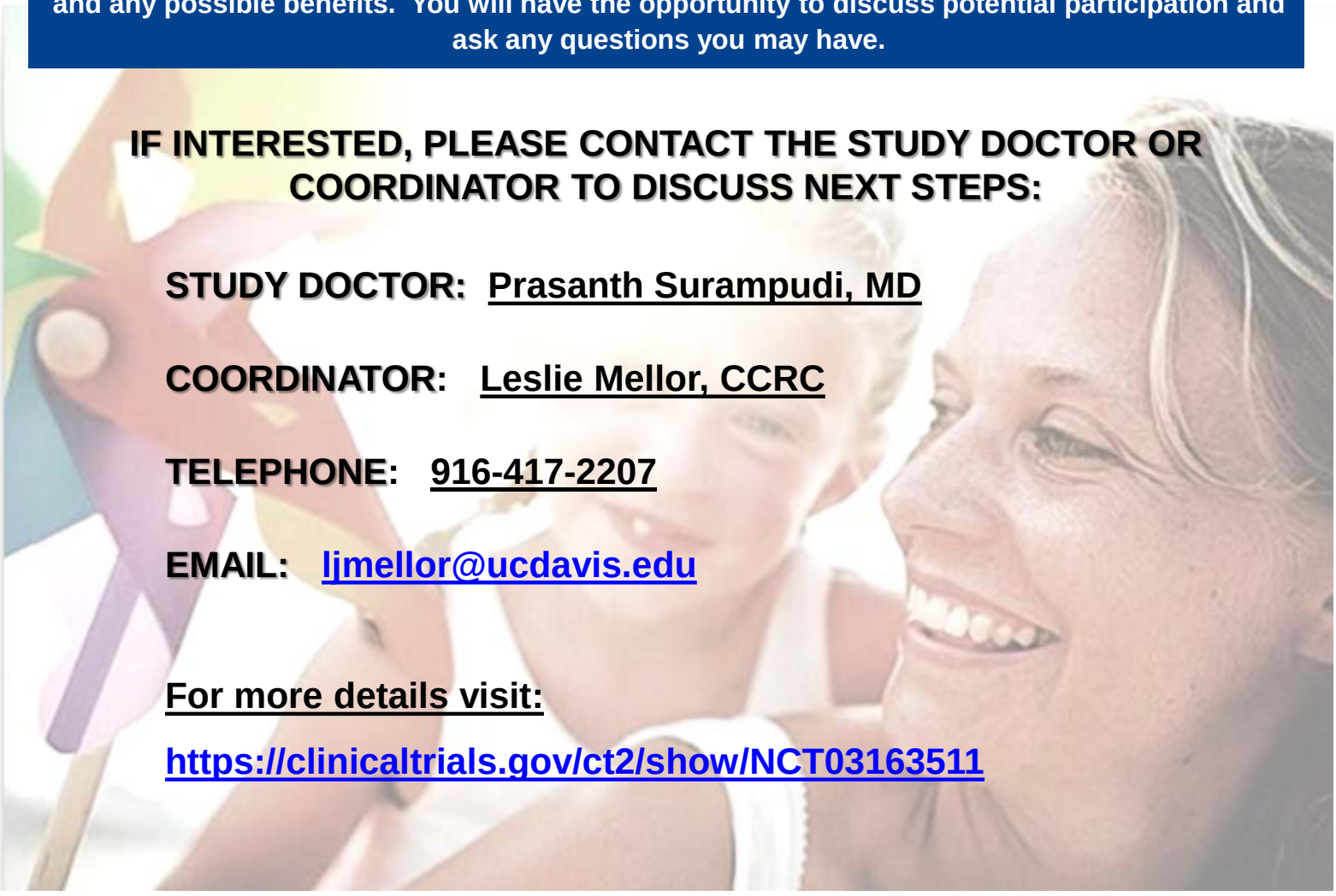
Are there Risks or Benefits?

As this is a first-in-human study, risks and benefits VC-02 are not fully known. All potential risks and benefits are outlined in the consent form and can be discussed further with the Study Doctor and Staff.

Are there costs involved?

There will be no charge for you to participate in the study. You will receive at no cost to you all study-related care, examinations, and medical testing from the study doctor. You will be provided with a blood glucose meter and a continuous glucose monitoring system, along with all associated supplies while you take part in the study. In addition, you will be compensated for your time and travel. Routine medical care for your condition (care you would have received whether or not you were in this study) will not be covered. Prescribed insulin and other diabetic medications are not investigational, and therefore, cannot be given to you as part of your study participation.

Before any study procedures take place, the Study Doctor and Study Staff will provide and review a detailed Informed Consent Form with you that explains all study procedures, risks and any possible benefits. You will have the opportunity to discuss potential participation and ask any questions you may have.



IF INTERESTED, PLEASE CONTACT THE STUDY DOCTOR OR COORDINATOR TO DISCUSS NEXT STEPS:

STUDY DOCTOR: Prasanth Surampudi, MD

COORDINATOR: Leslie Mellor, CCRC

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EMAIL: ljmellor@ucdavis.edu

For more details visit:

https://clinicaltrials.gov/ct2/show/NCT03163511