



**Mount
Sinai**

Artificial Pancreas Research Program



A pioneering clinical research program studying the efficacy of artificial pancreas (AP) systems to improve blood glucose control in people with type 1 diabetes (T1D) is underway at the Icahn School of Medicine at Mount Sinai. Under the leadership of Carol Levy, MD, Associate Professor of Medicine, Endocrinology, Diabetes and Bone Disease and Director of the Mount Sinai Diabetes Center and Type 1 Diabetes Clinical Research, the Artificial Pancreas Program is studying one of the most promising breakthroughs in type 1 diabetes treatment in decades.

Mount Sinai's research in this area has the potential to revolutionize the management of type 1 diabetes by paving the way for people with type 1 diabetes to use AP systems at home. Strong initial results have led to more studies supporting FDA approval. "The Artificial Pancreas Program at Mount Sinai holds the promise of freeing the patient from the burdens involved in self-care on a minute to minute basis, including frequent finger stick testing, careful monitoring of glucose sensor data, and regularly making insulin dose adjustments to reduce the risk of both high and low blood sugar levels," says Dr. Levy. "In short, these devices have the potential to result in better quality of life for people with T1D."

Initial Studies and Outcomes

Diabetes Assistant (DiA): The initial Artificial Pancreas trial at Mount Sinai began in October of 2014 and was the first of its kind in New York City. A collaboration among Mount Sinai, the University of Virginia (UVA) and Mayo Clinic, this study measured the ability of an automated, smart phone based AP system developed by UVA (known as the Diabetes Assistant or DiA) to normalize nighttime sugar levels in T1D patients. By combining a smart phone configured to act as a mini computer running a unique algorithm for controlling blood sugar levels, a glucose sensor and an insulin pump, the AP system is designed to maintain sugar levels without requiring patients to frequently test their blood sugar levels or inject insulin themselves. This JDRF funded study evaluated patients over five nights in a supervised hotel setting. Data revealed significantly improved overnight and daytime blood glucose control and less hypoglycemia.



RPI Collaboration: A recent study in collaboration with Stanford University and the Barbara Davis Diabetes Center evaluated a new AP system created by Rensselaer Polytechnic Institute (RPI). In this philanthropy funded study, patients wore the device 24/7 for three days, again in a supervised hotel setting. Participants ate meals without announcements and there was minimal patient input overall. Results showed improved glucose control, both day and night, and less hypoglycemia.

New Opportunities

To further advance artificial pancreas technology towards FDA approval and into the lives of people with diabetes, Dr. Levy and her team are continuing their artificial pancreas studies in collaboration with top-flight peer institutions locally and internationally.

Sensionics, Precise II Study: This study is currently ongoing and evaluates a first in class implanted glucose sensor that stays active for 90 days without being reinserted or reactivated. Current glucose sensors in the US remain active for no more than 7 days before needing to be reinserted and restarted. While this current sensor is active for 90 days, a new version is already planned that will be smaller and active for 180 days. These long term sensors offer greater freedom to patients and the hope is that they will be used as a part of the artificial pancreas system.

RPI Collaboration Follow-up: This is an out-patient follow-up to the original RPI Collaboration. Patients in the study will take the device home for two weeks and there will be an additional two week control period. The goal long term is to expand this study to younger adults and adolescents with T1D.

International Diabetes Closed Loop Trial (IDCL): This 10-site international study will trial another artificial pancreas system developed by UVA and refined for clinical use by TypeZero Technologies. Sites include Samsom Clinic, Stanford, Mayo Clinic, Barbara Davis Diabetes Center, Montpelier France, Amsterdam, University of Padova, and Harvard. These studies are expected to provide enough data to submit to the FDA for approval in order to bring the device to market.

Animas Hypoglycemia/Hyperglycemia Minimizer: This trial will evaluate a Johnson & Johnson product that uses a dexcom sensor and UVA based algorithm. This system will run using an insulin pump and a glucose sensor. We anticipate this study will open in the fall.

Future Studies Pending Funding

Diabetes Decision Support System: This study will evaluate a device that will communicate with physicians to provide additional real-time support to patients using pumps and injections. Although it is not specifically an AP study, it is evaluating important technology to improve care for T1D patients.

Technology and Seniors with T1D: This study will assess the best treatment regimens, including artificial pancreas, for people 60 years of age and older with T1D. The aim of this study is to evaluate more widespread use of technology in this group. A grant has been submitted to the NIH and funding notification is pending.

Future studies: There are several additional studies in development as part of the on-going Artificial Pancreas Research Program. These include a study of diabetes in pregnancy and the use of the AP system in this population to improve glucose control; further studies with RPI; and further evaluations of other methods of diabetes management support.

To learn more about Dr. Carol Levy and the Artificial Pancreas Research Program, please contact Pamela Heller, Senior Director of Development, at 646-605-8722 or pamela.heller@mountsinai.org.