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Principal Investigator	Michael Rickels, MD., MS
Study Title:	Automated Insulin Delivery in Elderly with Type 1 Diabetes (AIDE T1D): A Randomized Cross-over Trial Evaluating Automated Insulin Delivery Technologies on Hypoglycemia and Quality of Life in Elderly Adults with Type 1 Diabetes

Purpose:
This protocol plans to assess whether features of an automated insulin delivery system can reduce low blood glucose (hypoglycemia) in a population of older adults (65+) with type 1 diabetes (T1D).

This is a randomized crossover clinical trial. The study system will be the FDA approved Tandem t: slimX2 insulin pump integrated with the Dexcom G6 continuous glucose monitor (CGM). The study aims to determine its' effectiveness and safety through a comparison of two features: the hybrid closed loop (HCL) and the predictive low glucose insulin suspension (PLGS) to a control group using sensor-augmented pump (SAP) where the sensor and the pump are not linked to each other but are used separately.

Brief Description
Participant involvement will last approximately 54 weeks (~13 months). 3 diabetes centers in the United States will screen 200 people towards a goal of 90 completers. At the University of Pennsylvania, we expect to screen up to 50 people and a maximum of 30 will take part in the study.

If eligible, subjects will participate in a Run-in training phase. The length of the Run-in training phase will depend on each participant's learning curve needs. (I.e. what current insulin delivery method does each use...injections or a pump? What kind of pump do they use... t: slimX2 or another brand? Do they use / are they familiar with a CGM?)

After the Run-in / training period has been completed, enrolled subjects will enter the main crossover study and be assigned in random order to three 12-week periods:
1. The HCL intervention arm will utilize the Tandem t: slimX2 with Control-IQ Technology and Dexcom G6 CGM
2. The PLGS intervention arm will utilize the Tandem t: slimX2 with Basal-IQ Technology and Dexcom G6 CGM
3. The SAP control arm will utilize the Tandem t: slimX2 pump and Dexcom G6 CGM without HCL or PLGS features turned on. In other words, the sensor is used separately and will not communicate with the pump.
Once the last period of the main crossover trial has been completed, each participant will enter a 3-month Extension Phase where he/she will be given the choice to use the system as they would prefer... HCL, PLGS or SAP.

Eligibility
MAIN INCLUSION CRITERIA
-Clinical diagnosis of type 1 diabetes with a duration of at least 1 year
-Age ≥ 65 years old
-HbA1c < 10.0% s
-Insulin regimen involves basal/bolus insulin via insulin pump or multiple daily injections
-Most recent GFR ≥ 30 ml/min/m2
-Willingness to use a rapid acting insulin compatible with the Tandem t:slim X2 pump (currently aspart and lispro; other rapid acting insulins likely to be approved for pump use prior to study initiation such as Fiasp)
-Familiarity with and willingness to use a carbohydrate ratio for meal boluses
-Willing to use study devices and automated insulin delivery features
-Ability to download study devices at home or if not able to download at home willing to come into clinic to bring devices for download of data at visits and as needed for safety
-Participant is independently managing his/her diabetes with respect to insulin administration and glucose monitoring (may include assistance from spouse or other caregiver)
-At least 240 hours of CGM readings available during the end of run-in assessment
-At least 2% of time with CGM glucose levels < 70 mg/dL prior to SAP initiation
MAIN EXCLUSION CRITERIA

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-A condition, which in the opinion of the investigator or designee, would put the participant at risk, including severe vision or hearing impairment and any contraindication to the use of any of the study devices per FDA labeling
-Known adhesive allergy or skin reaction during the run-in pre-randomization phase or previous difficulty with pump and CGM insertions that would preclude participation in the randomized trial
-Concurrent use of any non-insulin glucose-lowering agent other than metformin (including GLP-1 agonists, Symlin, DPP-4 inhibitors, SGLT-2 inhibitors, sulfonylureas)
-Stage 4 or 5 renal disease
-The presence of a significant medical or psychiatric condition or use of a medication that in the judgment of the investigator may affect completion of any aspect of the protocol, or is likely to be associated with life expectancy of <1 year

Compensation (if applicable)
Participants in this study will receive $50 for each required visit that is completed in clinic or virtually (up to 9 visits).
1. Screening
2. Study System Initiation
3. Period 1 Week 4
4. Period 1 Week 12
5. Period 2 Week 4
6. Period 2 Week 12
7. Period 3 Week 4
8. Period 3 Week 12
9. Extension Period Week 12

At the University of Pennsylvania, participants will be paid in an ongoing manner as each visit is completed. The study team will provide a visa gift card to each participant at the screening visit and will load it throughout the study within 4 hours of visit completion (whether completed virtually or in person). In addition, parking tickets will be stamped for any visit conducted in University City.

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