



Canadian Clinical  
Trial Network  
*Accelerating Diabetes Breakthroughs*

## **Feasibility Assessment of Prototype Nocturnal Hypoglycemia Reduction System** Insulin pump suspension to prevent nocturnal hypoglycemia

### **Objective:**

The goal of this clinical study is to test software (algorithms) that reduce the rate of nocturnal hypoglycemia by temporarily suspending basal insulin delivery during the night in the home environment. Results from the study will expedite efforts to set up communication between a continuous glucose monitor (CGM) and an insulin pump.

### **Study Design:**

Initially, an inpatient study will be performed with overnight (USA) or daytime (Canada) admissions to test the safety and efficacy of the predictive algorithm.

Subsequently, an outpatient study will be performed with 48 subjects, 15 years of age and older with type 1 diabetes (T1D) for at least one year and using an insulin pump for at least six months. Clinical sites for this trial will be located in Canada (London, Ontario) and USA (Stanford and Denver).

Each patient will use the algorithm for 42 nights while at home. In a randomized fashion, if hypoglycemia is predicted, the algorithm will suspend the insulin pump delivery of insulin. Patients will be monitored for hypoglycemia, hyperglycemia, and treatment satisfaction, as well as ease of use.

### **Reason for Study:**

The Diabetes Control and Complications Trial showed that, despite its benefits, intensive diabetes treatment can increase the incidence of severe hypoglycemia by three times compared to the standard treatment. More than half of such events occurred during sleep hours. A full 75 per cent of hypoglycemic seizures in children occur during sleep. This international study will test an algorithm that forces insulin pumps to turn off during periods of hypoglycemia, where the wearer is unaware (i.e. at night) – a simple solution to a major problem for individuals wearing a pump.

This trial is a US-based study, for which JDRF CCTN is funding the addition of a Canadian site.

### **Study Contact:**

If you are interested in participating in the study, please contact the study coordinator to learn more about how to enrol.

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