

**Study Title:**

Postprandial glucose control using an extended bolus for high-fat high  
protein meals in a closed loop system in patients  
with  
Type 1 Diabetes

**NCT Number:**

NCT05454891

**ICF (Assent Form):**

V1.5

IRB approval date 02.06.2025

## **UNIVERSITY OF CALIFORNIA SAN FRANCISCO (UCSF)**

### **ASSENT TO PARTICIPATE IN A RESEARCH SUBJECT of using an extended bolus to cover a meal**

#### **For adolescents 13-17 years old**

#### **What is this study about?**

Laya Ekhlaspour and Eda Cengiz from the UCSF Department of Pediatrics, are doing a research study. The study will test if using an extended bolus (to deliver part of insulin now and part of the bolus slowly over a period) in adolescents with Type 1 diabetes who use a Tandem pump with Control IQ technology will help them control their blood sugar after breakfast.

The study doctors hope this type of bolus will help adolescents with Type 1 Diabetes have better blood sugar control, but they don't know if it will for sure. That's why they're doing the study.

Because you have Type 1 diabetes and use a Tandem pump with Control IQ technology, the doctors are asking if you want to be in this study.

#### **How many people will take part in this study?**

About 30 adolescents (older than 13 and younger than 18 years old), will be in this study.

#### **What will happen if you decide you might want to be in this research study?**

First, your parents will be asked if they give their permission for you to be in this study. They will also be asked if they agree to participate themselves, by doing some things like answering questions about you. If your parents don't agree, you cannot be in the study.

If your parents do agree, and you agree too, here's what will happen next:

#### **Before you begin the study:**

1. The study doctor will ask your parents some questions about you.
2. The study doctor will ask you questions about your health.

#### **ONLY GIRLS NEED TO READ THE NEXT SECTION:**

High or low blood sugars during pregnancy (having a baby) could harm the baby. Therefore, we want to make sure that nobody who is pregnant participates in the study.

It is possible for a girl who has had her first menstrual period and has started sexual activity to become pregnant. So if you have had your first menstrual period, whether you have had sexual activity or not, a urine test will be done at the first visit. We will not tell your parents if you have a positive pregnancy test without your permission.

### **During the study:**

The whole study will take 2-4 weeks.

During the first one to two weeks your study doctor will review your blood sugars.

After that, you eat breakfast (nut bar and protein shake) on two mornings. You should not eat or drink anything except water the night before starting 10 PM. During those days your study team will monitor your blood sugars for 5 hours. Following your breakfast, you should not eat any snacks or exercise.

Your parents will help make sure you take insulin before the breakfasts.

### **Will any parts of this study hurt or have other risks?**

Similar to your other days that you manage diabetes, you might have high or low blood sugars or allergies to tapes or pain with finger stick when you check your blood sugars.

### **Will you get better if you are in this study?**

We don't know if this study will help you have better blood sugar control.

### **What if you have questions?**

You can ask Dr. Laya Ekhlaspour or the people who work with them any questions you have about the study. You can ask your questions now or later, any time you like. You can also ask your parents to ask questions for you.

### **What are your choices?**

If your parents agree, you can be in this study if you want to. But you don't have to be in it if you don't want to. Nobody will get mad at you if you don't want to do this.

If you don't want to be in the study, you can continue the insulin management that you currently follow.

If you decide to be in the study now and you change your mind later, that's okay, too. You just have to tell the study doctor or the study staff as soon as you change your mind, and you will be taken out of the study.

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**If you don't want to be in this study, just say so, and don't sign this form.**

**If you want to be in this study, please sign your name below.**

**If you sign here, it means you agree to participate in this study.**

**The doctor will give you a copy of this form to keep.**

\_\_\_\_\_  
Adolescent's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Age

Adolescent's Name (*print*)

\_\_\_\_\_  
Signature of Person Conducting Assent Discussion

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Person Conducting Assent Discussion (*print*)