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:

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ICF (Adult Participant Consent):

V1.8

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UCSF
University of California
San Francisco

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

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

Research Project Director:	Laya Ekhlaspour, M.D., Assistant Professor of Pediatrics. UCSF, Room 309B, 500 Owens Street, San Francisco, CA. Phone:(415)514-8531; e-mail: laya.ekhlaspour@ucsf.edu

Study Coordinator:	Rebecca.Wesch@ucsf.edu, Phone: (415) 476-5984

This is a clinical research study. Your study doctor, Laya Ekhlaspour, MD, from the UCSF Department of Pediatrics will explain the study to you.

STUDY SUMMARY

Introduction: You are being asked to take part in a research study being done by Laya Ekhlaspour the study doctor/researcher at UCSF.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends, and health care team.

Purpose of the study: The purpose of this study is to learn whether an extended bolus (to deliver part of insulin now and part of the bolus slowly over a period) will improve blood glucose (sometimes called blood sugar) control after foods with high content of fat and protein.

Study Procedures: If you choose to be in this study, you will be asked to eat a standard breakfast (nut bar and protein shake) on two separate mornings and will be randomly (like flipping a coin) assigned to the order in which they receive the two treatments: extended followed by standard bolus or a standard followed by extended bolus before their meals. The blood sugars will be monitored for 5 hours following their breakfasts.

You will be in this study for about *four weeks or longer* and visit the research site approximately *once if needed.*

Possible Risks: There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

1) Hyperglycemia - High blood sugar and/or ketones.

2) Hypoglycemia – Low blood sugar

3) Loss of Privacy

We'll tell you about the other risks later in this consent form.

Possible Benefits:

You may benefit from participating in the study, but this cannot be guaranteed.

Your Other Options: You do not have to participate in this study. Your other choices may include getting standard care for diabetes without being in a study. You may continue with your current diabetes management regimen, or participate in other research studies

Please talk to your doctor about your choices before agreeing to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you:

- Have Type 1 Diabetes and have used insulin for at least one year
- Are older than 13 and younger than 19 years old
- Currently using the Control IQ closed-loop system

Also, you must not have:

- A1C >10%
- Current illness that would interfere with participation in the study
- Dietary restrictions that prevent test meal consumption
- Pregnancy

Your study doctor and staff will review more health-related requirements with you.

Why is this study being done?

The purpose of this study is to compare the effect of extended (deliver part of insulin now and part of the bolus slowly over a period, for example, 60% of the calculated dose to be given immediately and the rest over the period of 2 hrs) versus standard bolus on blood sugars after foods with high content of fat and protein.

Who pays for this study?

This study is being done by your study doctor and team. It is being paid by the National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK) through a grant that Dr. Ekhlaspour has received.

How many people will take part in this study?

About 30 participants will take part in this study. Up to 45 participants may be screened.

What will happen if I take part in this research study?

Before you begin the main part of the study:

Screening Visit

If you agree to participate, you will sign this consent form and you will sign an assent form. Then we will ask you some questions.

- Collection of information about you: This may include contact information, diabetes history, the most recent hemoglobin A1C, the past and current medical conditions, surgical procedures, allergies, medications and supplements, family history, and whether or not you have various symptoms. You will be asked about you pump settings and average daily insulin use over the past week. A pregnancy test will also be done for females.

The screening visit will last 1 to 2 hours. It can be done either in the clinic or virtually.

Run-in Period

During the first two to four weeks of the run-in period, your study doctor will review insulin and glucose data via t:connect, Tidepool and Dexcom Clarity and will use her clinical judgment to adjust the pump setting. The data review will be done remotely either on the phone or via zoom call.

You will be responsible for the adjustments recommended by the study team.

Randomization:
The visit may be in-clinic or virtual.

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in any group.

> If you are in group 1, on the first study day you will cover your breakfast with an extended bolus, and on the second study day will cover your breakfast with a standard bolus.
>
> If you are in group 2, on the first study day you will cover you breakfast with a standard bolus, and on the second study day will cover your breakfast with an extended bolus.

Main Study Procedures

On the day prior to the main phase, you will attend an in-person/virtual visit and your study doctor will provide all the instructions.

Following an overnight fast (starting at 10 pm), in the morning (between 6–8 am, within 1 hr of waking), at home, you will have breakfast. During the fasting period, you may have plain, unflavored water.

The insulin dose will be calculated based on the carbohydrate content of the meal and the Insulin to Carb Ratio using the Control IQ bolus calculator. For standard bolus, 100% of the dose will be given upfront (within 15 minutes before the meal start). For extended bolus, 60% of the insulin will be given upfront and 40% over 2 hrs.

To deliver an extended bolus, from the insulin pump's home screen, if you tap bolus, enter the amount of carbohydrates, then confirm the request, you can turn on the "extended bolus" feature. Once you tap 50% under DELIVER NOW, you can adjust the percentage of the food bolus that is to be delivered immediately. Then you tap 2 hours under duration.

You will be instructed that to avoid exercise in the evening prior to, or morning of the study day.

On the morning of the study day, you will have the study breakfast meal only if their pre-breakfast blood glucose is within the target range (70-180 mg/dl) and no insulin correction insulin dose or hypoglycemia treatment was given after 3 am the same morning.

Prior to meal consumption, you will be contacted by a research team member to confirm the requirements are met. The study staff will review the continuous glucose monitoring data. They will ask you to send a picture of the meal before and after breakfast as well.

After breakfast, you can have their routines except that they should avoid any physical

exercise and should not have any food or drink except for water for 5 hrs unless required to treat low blood sugar (confirmed by glucose meter ≤70 mg/dl).

At the end of each day, participants will be contacted by the same team member to review the study day events.

If the requirements are not met, the meal can be repeated up to five times.

After completion of the visits, you may continue using the system with the setting recommended during the study

The study meal includes KIRKLAND SIGNATURE Nut 2 Bars and 1.5 scoops of whey protein shake that contain 51.5 grams carbohydrates, 40.25 grams fat, and 54 grams of protein mixed with one cup of whole milk. We will provide the meals.

Monitoring:

You will be asked to share the glucose data via Dexcom clarity and upload data from the study pump during the study via t:connect and Tidepool.

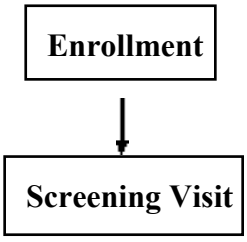
Blood sugars will be reviewed using Dexcom CLARITY® software (Dexcom Inc., San Diego, CA, USA) and Tidepool (Tidepool.org website and uploader).

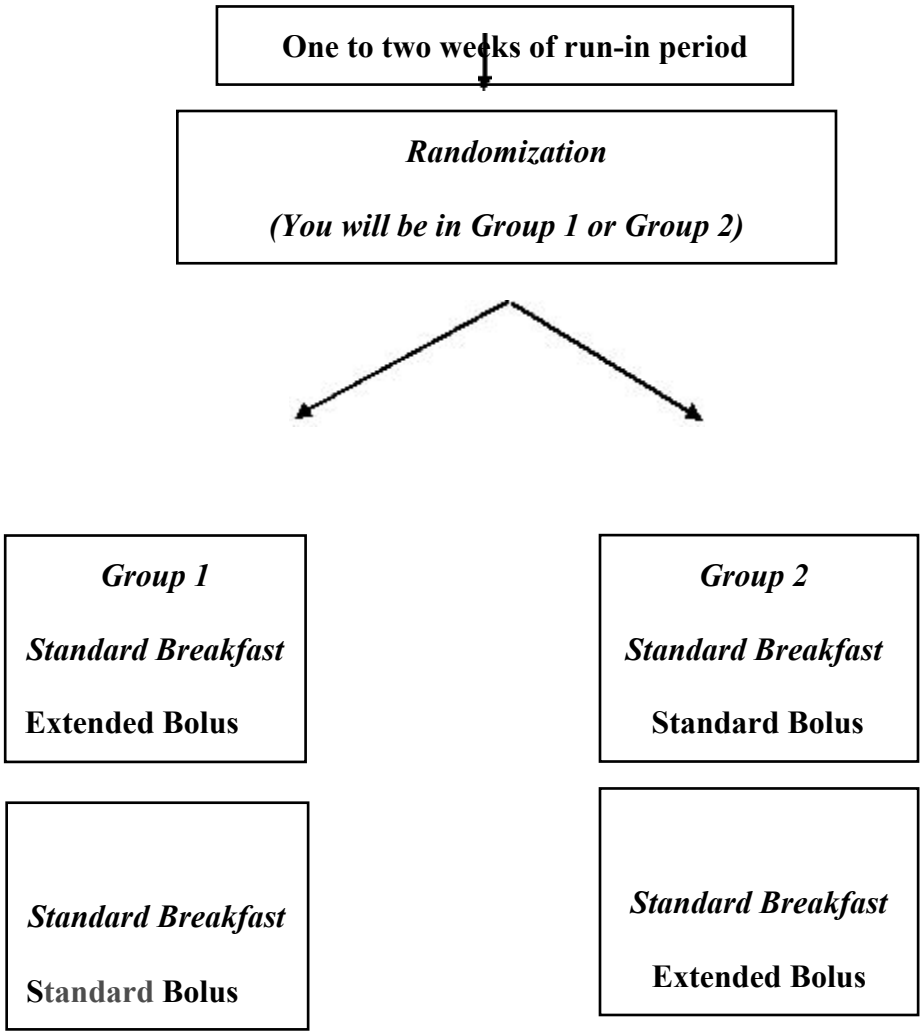
Insulin data will be reviewed using The t:connect® Diabetes Management Application (Tandem Diabetes Care, San Diego, CA) and Tidepool (Tidepool.org website and uploader).

Additional insulin dosing data might be needed for the study that is not available through t:connect, or tidepool. If this data are collected, the serial number of your insulin pump and the study dates will be given to Tandem Diabetes Care (the owners of the t:connect app), so that they can provide this data to the research team. Tandem Diabetes Care staff may see your name and date of birth that is kept as part of your account information for the t:connect app while extracting this data. Tandem will keep this identifiable information confidential and it will not be shared with anyone else or used for any other purpose as part of this research.

Study Chart

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.





How long will I be in the study?

Your will be asked to be in the study for around 4 weeks or until completion of study procedures.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. She will tell you how to stop your participation safely.

The study doctor may stop your from taking part in this study at any time if she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have risks while on the study. Everyone taking part in the study will be watched carefully for any risks. However, doctors don't know all the risks that may happen. Risks may be mild or very serious.

You should talk to your study doctor about any risks while taking part in the study.

Risks related to the *procedures* include those which are:

1) Risk of high blood sugar: High blood sugar and/or ketones could occur with prolongedpump suspension or with an infusion set failure, and high blood sugar can occur with largemeals.

The risk of low blood sugar: The frequency of low blood sugar should be no more and possibly less than it would be as part of daily living on an insulin pump. However, there may be a risk of low blood sugar following breakfast with a standard meal bolus, and the Control IQ system is designed to decrease the risk of low blood sugar. The insulin pump will suspend or decrease insulin delivery when there is a risk of low blood sugar.

Loss of Privacy – During the study we will collect identifiable data as well as the data from insulin pump, glucose sensor, and blood glucose meter. The study doctor and staff may use your contact information to call, text or email you during the study. They may use this information to discuss things like your pump settings or appointment reminders.

Unknown Risks: The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about having to participate in the study.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

The possible benefits are a better understanding of your diabetes management. You also may not benefit from this study, but that is what the study is trying to find out. Participants who take part in this research study will add to new knowledge that may help other people with type 1diabetes.

What other choices do we have if I do not take part in this study?

You do not have to participate in this study. Your other choices may include getting standard care for diabetes without being in a study. You may continue with your current diabetes management regimen, or participate in other research studies

Please talk to your doctor about your choices before deciding if you will take part in this study.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

----- Are you willing to be contacted about participating in future studies? □Yes □ No

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for them. Your signed consent form and some of their research tests will be added to their UCSF medical record.
Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records and may be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California
- Food and Drug Administration

Are there any costs to me for taking part in this study?

No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

Will I be paid for taking part in this study?

In return for your time, effort, and travel expenses, you will be paid *$150* for taking part in this study.

These payments will be paid as follows after the end of the study via gift card:

- Screening Visit: $25
- Run-in Visit/Randomization Visit: $25
- Meal Study: $50 for standard bolus day and $50 for extended bolus day

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Laya Ekhlaspour if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call her at (415)514-8531.

Treatment and Compensation for Injury: If your are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor Laya Ekhlaspour at (415) 514-8531.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at anytime.

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CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

_____ _____
Print Name of Participant

_____ _____
Date Signature of Participant

_____ _____
Date Person Obtaining Consent