**Mature Minor Participation Information Sheet**

Perth Children’s Hospital

|  |  |
| --- | --- |
| Title | Postprandial Glucose Excursions with Difficult Foods in Children with Type 1 Diabetes on Hybrid Closed Loop Therapy: A Pilot Study. |
| Short Title | HCL and Difficult Foods |
| Protocol Number | RGS0000003825 |
| Coordinating Principal Investigator | Dr Amelia Harray |
| Location | Telethon Kids Institute |

**1 Introduction**

You are invited to take part in a research project. The research is for young people with type 1 diabetes who are using hybrid closed loop therapy. The aim of the research is to look at how the hybrid closed loop system (Auto-Mode) deals with foods high in fat and protein, compared to standard pump therapy (Manual Mode).

This participation information sheet tells you about the research. It explains what you will be asked to do. Please read this information. Then ask questions about anything you want to know about the research.

You do not have to be part of the research. If you say no, you will still be looked after by the diabetes team at the hospital.

If you say yes, you will be asked to give your verbal consent. By agreeing, you are telling us that you:

• Understand what you have read.

• Consent to take part in the research project.

• Consent to eating the meals that are described.

• Consent to the use of your personal and health information as described.

**2 Why are we doing the research?**

There have been major improvements in the management of Type 1 Diabetes with technology in the form of hybrid closed loop (HCL) therapy. More people living with diabetes are choosing to use this therapy and we would like to know more about how the HCL system deals with foods high in fat and protein, which often cause delayed rises in blood glucose levels.

A recent survey of families attending the Diabetes Clinic has shown that people find it challenging to control glucose levels after eating pizza and pasta. Therefore, researchers would like to know whether the Medtronic 670G pump in Auto Mode (HCL therapy) better controls glucose levels than using it in Manual Mode when eating these foods.

We hope the study will give us information that we can use to give people advice to better deal with these difficult foods and provide researchers with knowledge to help guide future research studies.

**3 What will the study involve?**

The total time you will be involved in the research will be six to seven weeks. There will be no need for you to visit the Perth Children’s Hospital but you will be asked to talk to our research dietitian over the telephone and one online video call. Over the following two week-period, one of the research doctors will call you once or twice a week to ask about your glucose levels and help you to improve your insulin settings, this is called the ‘run in period’. You will participate in eight study days over the following four weeks in your own home. You won’t be paid to be part of the research, but we will repay you for things like travel and the meals.

**4 What will I be asked to do if I choose to take part in the research?**

You will be asked to attend one virtual digital clinic session with a research dietitian, which can be done from your home. During this session, you will be told what to do on the eight study days (over the following four weeks) and you will be able to ask questions about the study. You will talk to the Research Dietitian for education on how to bolus for foods high in fat and protein while on standard pump therapy. You will be provided with the money to purchase frozen meals from a supermarket of your choice. For two weeks following this visit, you will be called once or twice a week by one of the research doctors. They will help you to improve your insulin doses or insulin pump settings.

While you are participating in the study you will be asked to wear your continuous glucose monitor as much as possible and calibrate it twice a day with a blood glucose level. You will be asked to change the site of your insulin pump at least every three days.

On eight days over the four study weeks, you will be asked to eat a specified dinner meal high in protein and fat. Two pasta dishes and two pizza dishes in Auto-Mode (hybrid closed loop therapy) over two weeks, then repeating the meals in Manual-Mode (standard pump therapy). If you are unable to find one of the meals in your supermarket due to the COVID-19 pandemic, you can consume one of the test dinner meals (pizza/pasta) one week, and three the following week (maximum of three test meals per week). Meals can also be eaten on consecutive nights. As long as you have two pasta dishes and two pizza dishes in both Manual and Auto-Mode.

You will also be asked to;

* Check your blood glucose is between 3.9-10 mmol/L before starting the dinner meal
* Bolus insulin 15 minutes before the dinner meal
* Start to eat the test meal at roughly the same time on all eight study days (e.g. 6.30pm)
* Finish eating how much you want from the test meal within 20 minutes from when you started
* Avoid vigorous physical activity for three hours before and seven hours after the test dinner meal
* Not eat anything for seven hours after the test dinner meal.

If you have a blood glucose level less than 4mmol/l at any time, then you will have your usual hypo treatment. You will be asked to write down your blood glucose level before starting the dinner meal, insulin bolus, that day’s food and beverage intake, physical activity that day and any hypos experienced on the study day.

Depending on the study day, you will be advised to use either Manual- or Auto Mode and remain in that mode for seven hours after eating the test dinner meal. If you are asked to eat the test meal in Manual Mode, but usually use Auto Mode, it is asked that you switch to Manual Mode three hours before you start eating the test dinner meal.

On the other days of the four-week study period you will eat your usual meals and take your usual insulin. The researchers will ask to look at the glucose levels from your continuous glucose monitor on the study days, which can be seen online with your permission without you visiting the clinic.

**5 Who is carrying out the research?**

The researchers from the Children’s Diabetes Centre at Perth Children’s Hospital and Telethon Kids Institute are working together to do this research. Funding for the research has been provided by the Children’s Diabetes Centre.

**6 Do I have to take part in this research?**

You do not have to take part in this research. If you decide you do want to take part and then change your mind, you are free to pull out at any time. If you decide you don’t want to be part of the research anymore then please let us know. If you decide not to be part of the research, then it will not affect how you are looked after by the diabetes team at the hospital.

**7 Is there likely to be a benefit to me?**

We cannot promise that you will benefit from being part of the research. Some benefits may be:

* You will be given help to improve your insulin doses or insulin pump settings.
* You will learn about what happens to your glucose levels after ‘difficult meals’ while using hybrid closed loop therapy compared to standard pump therapy.
* You will receive education on how to bolus for foods high in fat and protein.

**8 What are the possible risks or side effects?**

High glucose levels and hypos sometimes happen with diabetes and they may happen during this research. While you are in Manual Mode you are to refrain from making any corrections for seven hours after eating the test meal, as we are looking at how your glucose levels respond in this timeframe. While you are in Auto Mode you will be advised to make corrections as directed by the system.

For hypoglycaemia (blood glucose level <4mmol/L) treat by giving 5-15g of fast acting carbohydrate immediately and check glucose levels in 15 to 30 minutes. For hyperglycaemia (blood glucose level >15mmol/L), please test for ketones and treat with insulin if ketone levels are >1mmol/L.

Please see the link below for hypoglycaemia and hypoglycaemia management

<https://diabetes.telethonkids.org.au/siteassets/media-docs---childrens-diabetes-centre/sickday.hypo.hypermanagement.pdf>

If these or any other side effects happen, or you are worried about them, please contact the research team and they will discuss with the study doctor.

**9 What will happen to my information?**

Any information about you that is collected as part of this research will be kept private. The information will be stored in a locked cupboard or on a computer that only the research team can access. The information will only be used for this research project. Any information that can identify you will be removed before the results of the research are shared with other people. You have the right to ask to see the information that has been collected about you as part of this research.

At the completion of the study, de-identified files will be archived and retained for at least fifteen years. Data will then be disposed of in accordance with Department of Health Patient Information Retention and Disposal Schedule.

**10 Who has approved the study?**

All research in Australia that involves humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This research project has been approved by the Child and Adolescent Health Service Human Research Ethics Committee. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**11 Who to contact if you have any complaints about the project or the way it is being conducted**

If you have any concerns about your rights as a participant in the study or you have a complaint about how the research is carried out, you can contact an independent person, the Executive Director Medical Services at Perth Children’s Hospital (Telephone No: 6456 2222). Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

If you suffer any injuries or complications because of this research project, you should contact the study team as soon as possible and we will help arrange medical treatment.

**12 Who to contact for more information about this study**

If you would like any more information about this study, please do not hesitate to contact a member of the research team. They are very happy to answer your questions.

**Contact person for the research team**

|  |  |
| --- | --- |
| Name | Dr Amelia Harray |
| Position | Coordinating Principal Investigator |
| Telephone | 0476 799 413 |
| Email | Amelia.Harray@health.wa.gov.au |

**Mature Minor Consent Form**

Perth Children’s Hospital

|  |  |
| --- | --- |
| Title | Postprandial Glucose Excursions with Difficult Foods in Children with Type 1 Diabetes on Hybrid Closed Loop Therapy: A Pilot Study. |
| Short Title | HCL and Difficult Foods |
| Protocol Number | RGS0000003825 |
| Coordinating Principal Investigator | Dr Amelia Harray |
| Location | Telethon Kids Institute |

**Declaration by Participant**

I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

|  |
| --- |
|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.