Local headed paper

Insulin Detemir versus Insulin Glargine in Young Women with Diabetes

Ethics Reference: Oxford REC A 07/H0604/122

Information Sheet for Parents Version 8:12/01/2013

Local details of PI

Invitation

Your daughter is being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen if your daughter participates.

Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

PART 1

Introduction

Type 1 diabetes occurs when the cells in the pancreas that produce insulin stop working. In order to control blood sugars, insulin has to be injected. There are 2 main types of insulin that can be injected, long acting and short acting. We are studying 2 relatively new long acting insulins. Insulin Detemir (Levemir) is a long acting insulin which may cause less weight gain than is seen with conventional long acting insulin (insulatard). Insulin Glargine (Lantus) is an alternative long acting insulin which is widely used in older children and adults with diabetes, but there is less information about its effect on weight gain. We want to compare Detemir and Glargine in young women with diabetes to see if there are differences in:

- Weight gain
- Blood glucose control
- Total daily amount of insulin
- Hypoglycaemia (hypos)

In addition we will measure levels of other hormones including testosterone which is made in small amounts in women, but may be increased in women with diabetes. Both of the insulins are already licensed for use in young people with diabetes.

What the study involves

If you and your daughter decide to take part in the study, she would be randomised to receive either insulin Detemir or insulin Glargine. This is done by a computer programme and she would have an equal chance of receiving either insulin. Randomisation is important to make the study as scientifically robust as possible. Once randomised, she would be able to see which insulin she was on. Both insulins would be given by injection from disposable pen devices.

- ***Visits, phone calls / Email and finger pricks***

The study lasts for 1 year and involves 6 clinic visits and regular telephone and/or email contact (minimum 12) between your daughter and the research nurse. At each visit we would measure height, weight, blood pressure and her waist and fill in a brief questionnaire about appetite. We can not pay you for taking part in the study but can reimburse you for additional expenses incurred as a result of taking part.

During the study it is important to have an accurate record of blood sugars. We would ask your daughter to check and record her blood sugar before breakfast, the evening meal and bedtime, and whenever she feels hypo as a minimum but the more information we have the better we are able to advise her. In addition, after 2 months, we would like her to record blood glucose values on a 5 point profile (breakfast, lunch, evening meal, bedtime and once overnight at around 0200h).

In centres with the necessary equipment after 3 months and at the very end of the study, we would like to record glucose values for 3 days using a sensing device. This device is a continuous glucose monitoring system. The sensor is a small electrode that lies just beneath the skin and can convert tiny amounts of glucose into a signal that is sent and stored by the monitor. Most people hardly notice they are wearing it. It will not display glucose at the time, but we will be able to download all the values after 3 days into a computer file that we can then print out. While the sensor is recording, the blood sugar needs to be tested at least 4 times a day to calibrate the sensor to ensure the most accurate results.

- ***Body Fat Investigations***

At the beginning and end of the study, where appropriate facilities are available, participants will be asked to have a DEXA scan to measure body fat distribution. It is not painful and, although it is a form of X-ray, the Dexa Scanner uses a low dose, equivalent to that received in about 24 hours from natural sources of radiation in the environment. The scan involves lying still on a bed while the scanner passes over the top of the person. It does not hurt and does not involve lying in an enclosed space. DEXA scans are not routinely performed if there is any chance of pregnancy and some centres may ask participants to do a pregnancy test before they scan. Your research Nurse will be able to tell you if this is the case at your hospital and if so will ask for a urine sample.

For Cambridge participants only. We would also like to look at body fat in more detail, measuring the amount of fat in liver and muscle using magnetic resonance

spectroscopy (MRS) and abdomen by magnetic resonance imagery (MRI).
These scans will be done in the same machine, one after the other. They use magnetic fields and radio signals to image the body, and do not involve X-rays or any radiation. The scans are painless, but loose metal objects such as a watch or jewellery should be removed and they should not be performed on anyone who has any metal implants within the body for example following surgery. The scans are noisy, and will take a total of 1 hour. People who do not like small spaces do not have to do this part of the study.

- ***Blood Tests***

4 times throughout the study; at the beginning, and end and after 3 and 6 months, we would like to take a blood sample to test for HbA1c (this assesses overall glucose control over the preceding 3 months) and levels of other hormones within the blood, such as testosterone, which may vary in young women with diabetes. Anyone can have anaesthetic cream applied to the skin before the blood test is done if they prefer.

- ***Insulin Doses***

During the first 4 weeks of the study, the study doctor or research nurse will make contact regularly by telephone (at least once a week or more frequently if necessary) to help adjust the insulin doses. Your daughter will start on 4 injections a day, with the long acting insulin given in the evening and her usual short acting insulin with meals throughout the day. **It may be necessary to add in a second injection of long acting insulin in the morning if the glucose levels remain high in the afternoon.**

- ***Other Things***

It is important that no-one who participates in the study becomes pregnant as the safety of neither insulin has been confirmed in pregnancy. Anyone participating in the study who could possibly become pregnant should use reliable method of contraception. Anyone who became pregnant unexpectedly during the study should inform the study team as soon as possible so that we can arrange any support and care needed.

PART 2

What if new information becomes available?

In the unlikely event of encountering any results during the study that could impact on your daughter's clinical care we will ask you if it is ok to inform your doctor.

What happens if I don't want to carry on?

You and your daughter can withdraw at any time without giving a reason. If you withdrew from the study, we will destroy all your identifiable samples, but we will ask you if we can use the data collected up to your withdrawal.

What if there is a problem?

Complaints

If you have a concern about any aspect of this study, you should ask the researchers who will do their best to answer your questions. If you wish to complain formally, you can contact the Patient Advice and Liaison Service (PALS), *(please insert local details)*

Harm

Although it is unlikely, if something does go wrong, and your daughter is harmed during the research due to someone's negligence, then you may have grounds for legal action against the Cambridge University NHS Foundation Trust but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

Will taking part be kept confidential?

Each person participating in this study will be given a unique study number, which will be used to identify the collected samples and their results by the team in Cambridge. They will not be able to identify your daughter from this number. A document linking the study number with names and addresses will be kept by your local consultant. Only the researchers directly involved in the study and representatives of the regulatory authorities for the purposes of audit will have access to the study results and your child's clinical records.
In compliance with the Data Protection Act, an anonymised copy of your study files will be kept at Cambridge in a locked room in the Department of Paediatrics and will be disposed of securely after 15 years. With your permission we would like to inform your GP of your daughter's participation in this study.

What will happen to any samples?

Samples will be stored in a locked room in the Department of Paediatrics until data analysis is completed and results are published, and for no more than 7 years.

What will happen to the study results?

Dr Rachel Williams, a Doctor under the supervision of Prof. David Dunger, will analyse the results. These results will be presented at scientific meetings and published in a scientific journal. No identifiable personal details will be used.
For Cambridge participants only. In addition to the scientific purposes of the study, the MRI scans will be looked at by specialist doctors in Addenbrooke's Hospital to double check that there are no abnormalities on them.

What happens if the young person says yes and the parents say no? or What happens if the young person says no and parents say yes?

We will try to ensure that both you and your daughter are happy with all parts of the study. If after hearing all the information you do not agree with your daughter's choice, we might ask another diabetes specialist doctor who is not involved with this study to speak to her. If that doctor feels she fully understands the reasons for entering or not entering the study, which ever is their choice, then we will go along with *their* wishes. If after reading this information sheet, and thinking it over for a few days and after discussing it with your child, you decide not to participate, then that is OK. It will not affect your daughter's treatment.

Who is organising the study?

The study is being organised by the Cambridge University Department of Paediatrics, based at Addenbrooke's Hospital

Who has reviewed the study?

This study has been reviewed by the Oxford Research Ethics Committee A (07/H0604/122).

Who should I contact if I have any questions?

If you have any questions regarding this study, please contact:
Dr << local investigator name>>
Tel << local phone no.>>
Email << local email address>>

Alternatively you can contact Dr Rachel Williams directly in Cambridge:Tel 01223 763404 e-mail rmw33@cam.ac.uk

And Finally…. thank you for taking the time to consider participating in this important research programme.