Insulin Detemir versus Insulin Glargine in Young Women with Diabetes

Ethics Reference: Oxford REC A 07/H0604/122

Information Sheet For Study Participants (>15yr) Version 8: 12/01/2013

<< local investigator details >>

Invitation

You are 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 you take part.

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, insulins, both long and short acting have to be injected. We are studying 2 relatively new long acting insulins. Insulin Detemir (Levemir) is 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 decide you wish to take part in the study, you will be randomised to receive either insulin Detemir or insulin Glargine. This will be done by a computer programme and you will have an equal chance of receiving either insulin. Randomisation is something we use to help compare 2 different treatment options. We put people into 2 groups and then compare them on the way through and at the end of the study. To make sure the groups are the same to begin with, we do this by chance (randomly). Once you

have been randomised, you will be able to tell which insulin you are giving. 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 you and the research nurse. At each visit we would like to measure your height, weight, blood pressure, take your waist measurement 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 your blood sugars. We would ask you to check and record your blood sugar before breakfast, your evening meal and before bedtime, and whenever you feel hypo as a minimum but the more information we have the better In addition, after 2 months, we would like you to record your blood glucose values on a 5 point profile (breakfast, lunch, evening meal, bedtime and once overnight at around 0200h).

In centres which have 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 tell you your 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 you are using the sensor you will need to test your blood sugar 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 you. It does not hurt and does not involve lying in an enclosed space. DEXA scans are not routinely performed if there is any chance you may be pregnant and some centres may ask you to do a pregnancy test before they do the 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 your liver and muscle using magnetic resonance spectroscopy (MRS) and your 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 you will be asked to remove loose metal objects such as a watch or jewellery and you should not have them if you have any metal implants within your body for example following surgery. They are noisy, but you can listen to music through headphones if you wish. The scans take 1 hour altogether. 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, your study doctor or research nurse will contact you regularly by telephone (at least once a week or more frequently if necessary) to help adjust your insulin doses. You will start on 4 injections a day, with the long acting insulin given in the evening and your 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 your glucose levels remain high in the afternoon.**

♥ ***Other Things***

If you decide to take part, it is important that you are not pregnant, and do not become pregnant during the study as the safety of neither insulin has been confirmed in pregnancy. Anyone participating in the study that could possibly get pregnant should use reliable methods 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?

If we encounter any results during the study that could impact on your 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 are free to withdraw at any time without giving a reason. If you withdraw 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 speak to the researchers who will do their best to answer your questions.

If you remain unhappy and 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 you are harmed during the research and this is due to someone's negligence, then you may have grounds for legal action for compensation 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 you 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 clinical records. In compliance with the Data Protection Act, an anonymised copy of your study file 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 participation in this study.

What will happen to any samples I give?

The blood samples will be stored securely in a locked room in the Department of Paediatrics until analysis of data is finished and results are published, and for no more than 7 years. All laboratory analyses will be done in Cambridge.

What will happen to the study results?

Dr Rachel Williams, a Doctor under the supervision of the chief investigator Prof. David Dunger, will lead the research group that is conducting the study, and 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.

Who is organising the study?

The study is being organised by the Cambridge University Department of Paediatrics, which is 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 talk to if I have any questions or concerns?

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 research