Local headed paper

Insulin Detemir versus Insulin Glargine in Young Women with Diabetes

Ethics Reference: Oxford REC A 07/H0604/122

Information Sheet for Study Participants (13-15yrs) Version 8: 12/01/2013

<Local PI details>

Invitation

We are asking you to help us with a research study. This leaflet explains why we are doing the research and what would happen to you if you decided to take part in the study.

Please take time to read this information sheet and discuss it with your parents and the doctors and nurses in the clinic.

Part 1 tells you about why we want to do the study and what will happen if you take part.

Part 2 gives you more detailed information about how we plan to run the study.

PART 1

♥ ***Introduction***

Diabetes is caused when the cells in the pancreas that make insulin stop working. When this happens, you need to inject insulin to make sure that your blood sugar levels stay normal. Most people use a long acting insulin to give a continuous low level in the blood stream and a short acting insulin to give a "boost" at meal times.

There are several different types of insulin made and we want to study differences between 2 relatively new insulins, called Detemir (or Levemir) and another one called Glargine (or Lantus). Both have been tested and are already being used by other young women, so we already know they are safe. Although it is normal to gain weight as you get older, girls with diabetes may have more weight gain than girls without diabetes. Levemir appears to cause less weight gain than insulatard (the conventional 'cloudy' long acting insulin) in adults and young people with diabetes, but it has never been compared with Lantus in girls of your age. This study will look closely at weight gain and body fat distribution to see whether there are any differences between the 2 insulins, along with any differences in your blood sugar control, how many hypos you have and the levels of other hormones such as testosterone, which is made both in girls and boys although in smaller amounts in girls but the amount can be slightly increased in girls with diabetes.

♥ ***Why have I been invited?***

We are asking all girls over the age of 13 who have reached puberty to take part. The study is being carried out in several other diabetes clinics in the United Kingdom in addition to this one.

♥ ***Do I have to take part?***

NO, you do not have to take part in the study if you don't want to. This information sheet explains what taking part in the study would involve. We will spend as much as time as you need discussing the study with you and your family. You may also want to ask other people such as your GP what they think.

If you want to take part in the study you would sign a form called an 'assent' form and your parents would sign a consent form indicating you are both happy to go ahead. You can change your mind at any time without telling us why. Whether or not you join the study will not affect your relationship with the clinic doctor or the nurse.

♥ ***What happens if I decide to take part?***

If you decide you wish to take part in the study, you will be randomised to receive either insulin Detemir or insulin Glargine. 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 pens.

♥ ***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 measure your height, weight, blood pressure, take your waist measurement and fill in a brief questionnaire about appetite. There is no payment for participating in the study, but we will be able to pay you back for any additional expenses from 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 at least 3 times a day (before breakfast, your evening meal and before bedtime) so whenever you feel hypo but the more information we have the better! In addition, after 2 months, we would like you to record your blood glucose values 5 times during one day (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 use a special sensor to monitor your blood sugar levels over 3 days. The sensor sits under the skin and records blood sugars in a small box about the size of a mobile phone. You would not be able to see you sugars at the time, but the doctors can download them into a computer and see much more detail about blood sugars and how they vary throughout the day. While the sensor is being used, you would need to test your blood sugar at least 4 times a day in order to get accurate results.

- ***Body Fat Investigations***

At the beginning and end of the study, where appropriate facilities are available, participants will be asked to have something called a DEXA scan which will give detailed information about body fat. During the scan, you would need to lie very still on a bed while the scanner goes over you. It is not painful and, although it is a form of X-ray, the dose is very low, about the same as you would be exposed to in about 24 hours from natural sources of radiation in the environment. 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 ask you to provide a urine sample

For Cambridge patients only. We would also like to look at body fat in more detail, measuring the amount of fat in your liver and muscle using a special scan called an MRI. These scans use magnetic fields and radio signals to image the body, and do not involve X-rays. The scans are painless, but you will be asked to remove 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 your average blood sugars over the last 3 months) and levels of other hormones within the blood, such as testosterone, which may vary in young women with diabetes. If you prefer you can have magic cream applied to the skin before the blood test is done.

- ***Insulin Doses***

During the first 4 weeks of the study, your study doctor or research nurse will phone you regularly to help adjust your insulin doses. You would start on 4 injections a day, with the long acting insulin given in the evening and your usual short acting insulin with meals. *You may be asked to have a second injection of long acting insulin in the morning if your glucose levels remain high in the afternoon.*

- ***Is there anything else to think about?***

It is important that none of the young women who decide to take part in this study become pregnant as we don't know whether the insulins are safe for unborn babies. We do not expect anyone who goes ahead with the study to become pregnant but would ask that if anyone were to become unexpectedly pregnant during the study that they tell us immediately so that we can arrange any support and care needed. Anyone taking part in the study who could possibly become pregnant, should use a reliable method of contraception..

Part 2

What happens to the blood?

The blood will be sent to the scientists in Cambridge who will let your doctor know the results to help them look after you. We will also let you and your parents know how the study is going.

For Cambridge participants only - What happens to the MRI pictures?

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 to information about me?

The nurse who takes your blood will not give the scientists your name. A special number will be put onto the blood sample instead. Your name will not be given to anyone working outside of the hospital where you have your blood sample taken.

What do I do next?

When you have read this leaflet, think about it for a while and talk about it with your parents. If you have any more questions, don't be afraid to ask your nurse or the doctor at the clinic. You can e-mail your questions to Dr Rachel Williams who is organizing the study: rmw33@cam.ac.uk or phone her on 01223 763404.

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And finally: Thank-you for reading this leaflet! Take as much time to think about it as you wish and if you have anything you wish to ask please contact Rachel Williams (Tel: 01223 763404 or rmw33@cam.ac.uk) or the local team:

Dr Insert local details
Tel
Email