Have you ever taken Victoza, Byetta or Lyxumia?

UNIVERSITY OF DUNDEE

Are you one of the following patients?

I started my injections less than 1 year ago.
AND
I am interested in taking part in a research study

NHS Tayside

Call us on
xxxx (Name)
xxxx (Name)
to find out more

DIRECT– GLP-1 Study

Short Patient Information Sheet (Group B)
Version 1 29 January 2013

Why are we conducting this research?

Victoza, Byetta and Lyxumia can have dramatic results in terms of stabilising blood sugar and helping with weight loss. However some patients' blood sugar levels do not improve very much following these injections. We are therefore looking to see if there is anything special in the urine or blood of patients who respond to these injections differently.

What does the research involve?

Participation will take 3 separate outpatient visits spaced over a period of between 2 weeks to 1 month apart.

At the first visit we will ask for your permission (giving consent) for the research team to review your medical details to see how well you responded to Victoza, Byetta or Lyxumia.

If your response over the first 6 months of treatment with Victoza (or Byetta or Lyxumia) fits our criteria we will ask you to complete a short **interview** with a research nurse about your diabetes lasting about 30 minutes.

We will then ask you to come for 2 further visits spaced between 3 and 5 days apart, on dates that are convenient for you within the following month. These visits will involve **blood samples** taken through a cannula (a fine plastic tube that is inserted into a vein using a fine needle) before and after an energy milkshake drink. At the third visit you'll need to have a cannula placed in both arms to allow a solution of glucose to be attached to one cannula for 1 hour. After 1 hour this is swapped for a GLP-1 solution for a further 1 hour. A GLP-1 solution has the same effect as taking Victoza, Byetta or Lyxumia.

You will be asked to stop some of your diabetes medications for a short time before these 2 visits, but otherwise your usual clinical care team will look after your treatment as they usually do. Both these visits will take about 4-5 hours and will take place in the morning. You will receive your lunch at the end of the tests on both these days.

Are there any risks or benefits of taking part?

Donation of blood samples can be uncomfortable but this procedure will be carried out by an experienced nurse to minimise any discomfort. You will be required to stop some of your diabetes medication prior to visits 2 and 3. This will only be up to a maximum of 3 days and should not cause you any health problems. Stopping medication temporarily is often done in diabetes research studies. There is a small chance that your blood sugar will rise enough to make you feel thirsty or to pass a lot of urine. If you feel unwell in any way during this time and if your blood sugar is high, we will ask you to start taking your treatment again and you will be withdrawn from the study.

The project is unlikely to benefit individuals directly but will help improve understanding and future treatment of diabetes.

Who is funding and organising this research?

This project is being run by The University of Dundee. It is part of a European-wide project called DIRECT which aims to improve the treatment of Type 2 diabetes by finding the right treatment, at the right time for each individual. The funders are the Innovative Medicine Initiative – Joint Understanding (IMI-JU).

Who has reviewed this study?

This Project has been reviewed by the East of Scotland Research Ethics Service.

What about travel expenses?

Your travel expenses will be reimbursed in full and we will offer you door to door taxis for the 2 longer visits.

NHS Tayside

Do I have to take part in this study?

No, participation is entirely voluntary. It is up to you to decide to join the study. If you agree to take part, we will ask you to sign a consent form. You are free to withdraw at any point.
Participation in the study will not effect your treatment as an NHS patient.

Will my participation be kept confidential?

We will tell your GP that you are participating in the study. All information shared with researchers will be coded, so only those nurses seeing you will have access to your name and contact details.

How can I find out more about this project?

For more information about this project, please contact our study co-ordinator or study nurse:

(Study Role
Name Telephone: xxxxx)

(Study Role
Name Telephone: xxxxx)