WOULD I BENEFIT FROM TAKING PART?

The results of this study will potentially improve the care that people with type 2 diabetes receive in the future. Your own diabetes control might improve due to the addition of a new medication and you would receive advice on blood sugar control throughout the study period.

DO I HAVE TO TAKE PART?

Participation is entirely voluntary. If you do not wish to take part you may do so without justifying your decision and your future diabetes care and treatment would not be affected. If you decided to join the study, you would still be free to change your mind at any time during the study.

WOULD I BE PAID FOR TAKING PART?

Participants will be given £50 after attending the first sessions at the beginning of the study and a further £50 at the end of the study for the inconvenience and to acknowledge your involvement in the study. In addition travelling expenses will be refunded.

WHAT DO I DO IF I AM INTERESTED IN TAKING PART?

If you are interested in finding out more, **please complete the reply slip and return it to the Research team or contact the team directly using the details at the end of this leaflet**.

A member of the team will contact you to tell you about the study and answer any questions you may have. If you are interested in taking part they will arrange an appointment with the study clinician.

At this stage you will be sent a full Patient Information Leaflet which describes exactly what the study involves along with leaflets describing the study MRI scan and exercise test. If you decide to take part, your written informed consent will be taken when you meet the study clinician.

If you have anything you would like to ask the study team, please contact us and we will be happy to help.

Sarah Edwards - LYDIA Project Manager
T: 0116 258 8637 (8:30am - 4.30pm)
email: LYDIA@le.ac.uk

Dr Zin Zin Htike - LYDIA Study Clinician
T: 07732 648323 (9am - 5pm)
email: zin.htike@uhl-tr.nhs.uk

Leicester Diabetes Centre
Leicester General Hospital, LE5 4PW

Thank you for taking the time to read this leaflet

University of Leicester

University Hospitals of Leicester NHS
NHS Trust

LYDIA Invitation leaflet (V3 10/02/2014)

LYDIA

Patient Invitation Leaflet

Are you interested in taking part in a research study on cardiac function in people with type 2 diabetes?

Leicester Diabetes Centre
Committed to Growing International Research, Education & Innovation

INTRODUCTION

In general, people who develop type 2 diabetes are aged over 50 years. However the number of people who are developing it at an earlier age has been increasing. Research has shown that type 2 diabetes may be more aggressive in this group compared to people who are older. Most worrying is the effect on the health of their heart. Research suggests they are more likely to have a heart attack or reduced heart function (an early risk factor for heart failure) and that mortality is higher in this group. It is therefore very important that younger adults with type 2 diabetes receive the best treatment.

Incretins are a new type of medicine frequently prescribed for people with type 2 diabetes whose blood sugars remain high, despite taking one or more medicines for their diabetes. Unlike other diabetes medications, this type of drug has a role in controlling blood sugar level without weight gain and actually results in weight loss in many patients or no change in weight.
Recently these new medications are thought to have a positive effect on the functioning and structure of the heart. As a result they may be particularly useful for younger adults who are at a higher risk of having a heart attack or heart failure because of their diabetes.

The study will compare two of these new medicines (liraglutide and sitagliptin) to see which has the best effect on the heart, in addition to their role in stabilising the sugar in the blood.

WHO CAN TAKE PART IN THE STUDY?

You **need** to be **aged** between **18 and 50 years** (inclusive) and have **type 2 diabetes**. You **can't be taking insulin** or any of the **study drugs** (**Liraglutide**/ **Exenatide**/ **Bydureon**/ **Lixisenatide**/ **Sitagliptin**/ **Saxagliptin**/ **Vildagliptin**/ **Linagliptin**).If you fit this criteria you may be suitable to take part. You will also need to fulfil some other requirements and these will be checked by the study team.

WHAT WOULD TAKING PART INVOLVE?

Taking part would involve attending a number of appointments at Leicester General Hospital and at the Glenfield Hospital. At the first appointment you would meet with the study clinician who would explain exactly what the study involves and if you were interested in taking part your written informed consent would be taken.

After the consent visit you would need to attend six appointments spread over the six month study period. During these, various clinical measures would be made, some of which you will be familiar with. In addition an MRI scan would be carried out at the beginning and end of the study to provide a measure of your heart (cardiac) function. Your cardiac fitness would also be assessed in a test which involved you exercising on a stationary bicycle while your oxygen consumption and heart rate were measured. Before you came to the consent visit you would be sent an information leaflet explaining in detail what the study involves. This would give you a chance to read about the study before the appointment where you can ask any questions.

PRESCRIPTION OF A DRUG THERAPY

If you joined the study you would be randomly picked to take either sitagliptin (a tablet) or liraglutide (a medication administered using an injection pen) for a total of 6 months. Your diabetes control and general health would be reviewed throughout the study to make sure that you are suitable to take the medicine and that you are responding well to it. Any possible side effects would be fully explained to you by the study clinician and you would be provided with an information sheet about the medication you were taking and the tests performed.

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