University of Exeter

NHS
Royal Devon University Healthcare
NHS Foundation Trust

ENDURE

Understanding beta cell disorders through the study of rare genotypes

A research study helping scientists to understand the causes and implications of making too little or too much insulin.

Could you spare some time to help researchers better understand the causes and effects of genetic changes altering insulin production?

wellcome

THE LEONA M. AND HARRY B. HELMSLEY CHARITABLE TRUST

DIABETES UK
KNOW DIABETES. FIGHT DIABETES.

JDRF IMPROVING LIVES. CURING TYPE 1 DIABETES.

Chief Investigator: Professor Andrew Hattersley

ENDURE Study – Core Information Leaflet

Why are we doing this research?

Insulin is a type of messenger in blood that lowers blood sugar levels after a meal. It is made by special cells called beta cells. In some people, the beta cells don't work properly because they have a spelling change in their genetic code, which is the instruction book that tells the body how to make things.
We would like to understand how these changes change how the body works.

Why am I being invited?

You have been invited into this study because you have one of the spelling changes that means the beta cells don't work properly, or because you are a 'healthy control'. We want to check if the body works differently in people with these spelling changes in their genetic code compare to people without them.

What does participation involve?

Please refer to the Core Study Flowchart describing the visit, including timings and details of the measures and tests that we would like you to participate in. You will be able to discuss the study with a member of the study team and ask any questions you have. The research visit will take place in England at the NIHR Exeter Clinical Research Facility or possibly, depending on where you live, at a different location. You will be asked to sign a form to say that you agree to take part in the study and for your samples to be given to the study to be used for research purposes (please see the back page of this leaflet for the questions you will be asked).

During the visit we will ask you and your parents/guardians questions about your health. We will measure your height and weight and collect some blood samples. You might be asked to take part in extra parts of the study that will look at the effects of the spelling changes in more detail. For example, if you are invited for the Imaging Sub-Study, we will explain to you exactly what is involved and will also give you the Imaging Sub-Study Flowchart.

A small number of people may be asked to come back for more tests and we will explain that if we need to ask you to.

Who is organising and funding this research?

The research will be managed through the NIHR Exeter Clinical Research Facility (Exeter CRF), which is funded by the National Institute for Health and Care Research, a part of the NHS, and a collaboration with the University of Exeter. Providers of additional funding for the study include the Wellcome Trust, Diabetes UK and JDRF International, and The Leona M. and Harry B. Helmsley Charitable Trust.

What will happen to my samples and data?

A study number will be created that is only for you. We will use this on all of your samples and data. We will make sure that all of your data is looked after in a very secure way to protect it and make sure that no-one can identify you from it.

Some of your samples will be sent for testing at the laboratories at the hospital in Exeter (The Royal Devon and Exeter Hospital) with the information needed by the National Health Service (NHS).

We will do tests on the samples to understand how genetic spelling changes can change the cells in the body.

We will also ask you if it is OK to put your samples and data into a 'research bank' (https://www.diabetesgenes.org/current-research/genetic-beta-cell-research-bank/) to store them safely for use in future research studies. This is optional. If you don't want to do this, we can safely get rid of your samples and data at the end of this study.

If we find out new things by doing this study, we will write about it in articles for other researchers. We will always make sure that you cannot be identified from what we write, and that no one can tell that you took part in the study.

Where can I find out more?

For further information about the study, please contact a member of our study team on:

+44 (0)1392 408181 Email: lynseybeall@nhs.net

Additional information can be found on the study website:
https://www.diabetesgenes.org/current-research/endure-study/

Who has reviewed this study?

This study has been reviewed and approved by the North West – Greater Manchester East Research Ethics Committee and the Health Research Authority (HRA).

ENDURE Core Study Flowchart		
ENDURE **Understanding beta cell disorders through the study of rare genotypes**		**Cohort:** **CORE**
What will happen during my research appointment?		
	What does this involve?	**Are there any risks?**
Arrive at Clinical Research Facility or chosen location **Give consent to participate** **15 -20 mins**	At the time of making your appointment, you will be asked if you require a parking permit. At your visit, a member of the study research team will discuss all aspects of the study with you. You will have the opportunity to ask questions and when you are happy that you understand what is involved, you will be asked to complete a form giving your consent to participate in the study.	No. Participation is entirely voluntary and it is up to you whether to join the study and you can withdraw at any time without giving a reason.
Body measurements, medical history **15 - 20 mins**	You will be asked some questions about your general health and any treatments, plus family history of diabetes. We will measure and record your height and weight.	No.
Blood collection **5 - 10 mins**	We will insert a small cannula (thin plastic tube) into your arm to make the collection of blood samples more comfortable. The blood sampling will involve a single draw of blood. The exact number of blood samples vary for different individuals so will be explained in advance. The total amount of blood we will collect during the visit will follow WHO guidelines which factor for age and weight. An 11-15 y child's sample will not exceed 44 millilitres (ml) (approx 2½ tbsp). The blood will be analysed to assess how genetic variants affect function and features of cells in the body. Immune system, genetic and insulin markers will be measured.	Blood sampling can cause some discomfort when the needle is placed in the vein to draw blood. There is also a possibility that a small bruise may develop. These risks will be minimised by the procedures being carried out by a qualified nurse/researcher who will monitor you closely throughout the whole procedure.
END OF STUDY	A member of the research team will make sure that you are comfortable before you leave the research facility.	

Do I have to take part in this study?

No, it is totally up to you to decide whether you want to take part and you will have at least 24 hours to decide and can ask for more time if you would like to. If you decide to take part, we will ask you to show us this by writing your name on a form (please look at the back page of this leaflet to see what we will ask you). You can change your mind, and stop taking part, at any time without telling us why.

Are there any risks or benefits in taking part?

There may be no direct benefit from taking part in the ENDURE study. You won't be paid for taking part but the person looking after you will be paid back any costs related to you both coming to the study visit. If we find anything that your usual doctor or nurse should know about, we will tell them and they may want to see you.

Giving of blood samples can be uncomfortable but this will be done by an experienced nurse or doctor and, if you would like, we can put some special cream or spray on your arm so that you don't feel it when we take the blood sample.

What if there is a problem?

Should you have a problem, please ask the person who looks after you to contact the research team. If you are unhappy with how you have been treated whilst taking part in this study but don't wish to discuss it with the research team directly, the RD&E Patient Engagement/Patient Advice & Liaison Service (PALS) team will provide independent advice: The PALS Office, Royal Devon & Exeter Hospital (Wonford), Barrack Road, Exeter EX2 5DW, +44 (0)1392 402093.

General Data Protection Regulation ('GDPR') and your rights

This information sheet gives you information that you need to receive due to changes in the UK law. The person who looks after you has an information sheet with the full details that you can look at if you want to.

The University of Exeter will look after your personal data securely and this has also been explained to the person who looks after you.

If you have any questions about the University of Exeter's processing of your personal data that cannot be answered by the research team, you can contact the University's Data Protection Officer at: https://www.exeter.ac.uk/aboutoursite/dataprotection/dpo/ .

If you have any worries about how the data is controlled and managed for this study, then please contact the Sponsor Representative, Dr Antony Walsh, Head of Research Governance, Ethics and Compliance, University of Exeter, Tel: +44 (0)1392 726621 or Email: res-sponsor@exeter.ac.uk .

Thank you for reading this leaflet, which is yours to keep.

If you wish to participate in this study, you will be asked to sign an assent form in the presence of a member of the research team/your usual clinical team, a copy of which you will be given to keep.

The form will include the following statements:

ASSENT STATEMENTS

I have been given the ENDURE Core study information leaflet to keep and I have read it or had it read to me.

I have asked all the questions I want to and my questions have been answered in a way I understand.

I agree to take part in this study.

I understand that I can change my mind at any time and stop being part of the study.

Optional Assent Statements:

You can say 'No' to the next statements and still take part in the study.

I agree for my information and any leftover samples to be kept for use in other studies.

I am happy to be contacted about research in the future.