adAPT autoimmune diabetes ACCELERATOR PREVENTION TRIAL

PARTICIPANT 16yrs INFORMATION SHEET - SCREENING

INVITATION TO TAKE PART

We would like to invite you to take part in an exciting new type 1 diabetes prevention study which may be of value to you and your family.

Before you decide whether or not you wish to participate, we would like you to understand why we are doing it, and what it would involve if you agreed. Please take time to read the information below, and to discuss it with friends, family and your own doctor. At the foot of this leaflet you will find space to write down questions you may wish to ask the study doctor or research nurse. We will do our best to explain and provide any further information you may ask now or later. Take your time to decide if you wish to take part.

This study involves a screening phase to identify young people at risk of type 1 diabetes, and treatment stages to try and prevent the disease for those who are. For the moment, you are being invited to take part in the screening phase of the study.

WHY ARE WE CONDUCTING THIS STUDY?

At present, there is no treatment that can prevent type 1 diabetes. We know that more children each year are developing the disorder, and want to find a way to stop this trend.

In this research project we want to find out if we can prevent children at high risk of developing type 1 diabetes from needing insulin, by treating them with a medicine called metformin. We think metformin will help children at risk of developing type 1 diabetes because it will stop their insulin cells from working too hard, which could then protect them from the damage that would eventually lead to the children needing to inject insulin.

We can tell from a small blood test if you are at high risk of developing diabetes. The treatment stages of adAPT will attempt to prevent the onset of diabetes in people in this higher risk group.

The blood test detects diabetes related antibodies in the blood. Antiantibodies are proteins that are made by the body's immune system. Two or more antibody types is considered a positive result. Testing positive does not mean you will definitely get

diabetes, but your chances are much greater than if you tested negative. We anticipate a positive result in 1 in every 20 children that we test (see Chart 1, below).

WHY AM I BEING ASKED TO TAKE PART?

We think this study might be of interest to you because you have a brother, sister or parent who was diagnosed with diabetes before the age of 25y. Your chances of developing diabetes are small, but nevertheless greater than normal because of the family connection.

We hope to screen approximately 3500 children and young adults just like you from Scotland and England.

DO I HAVE TO TAKE PART?

No. Participation is entirely voluntary, and you are free to turn down this invitation or withdraw from the study at any time, without giving us a reason. The decision to participate in this study will not affect the medical care you or your family receive, nor the relationship that you have with your doctors or nurses. If you, the study doctor, or another health professional decides you should withdraw from the study, we would like your permission to keep and analyse the data we have already collected.

WHAT WILL THE STUDY INVOLVE?

We will invite you to attend a visit with the research team, which will be at one of your local hospitals.

This visit will take less than an hour, but it can take longer if you require additional time.

During the visit we will discuss the study in detail and answer any questions you may have.
We will ask you to sign a consent form to show that you are happy to take part (you will be given a copy to take home.)

We will ask a few questions about your general health and any medicines you may be taking. This is to ensure that the study is appropriate for you.

We will take a small blood sample (3.5mls, less than a teaspoon) from your arm. We will numb the skin before we take the sample (see below).

We will send your blood sample anonymously to a laboratory for antibody testing. The results will be available 8 weeks after the visit.

We will send you a letter reporting the antibody result. If the result is negative (we expect this in 95% of the children) you do not require any further study visits.

If the test is positive, the study doctor will contact you by telephone to discuss the result, and make an appointment to see you to discuss the result further. We will also send a results letter and an information sheet for the Treatment Trial (Stages 1 & 2) which will be discussed at your results visit.

Even if you do not wish to take part in the Treatment Trial you should still discuss the results with the study doctor.

ARE THERE ANY DISCOMFORTS OR RISKS TO TAKING PART?

There are no risks to taking part in this part of the study. The blood sample may cause slight discomfort. However, we offer an anaesthetic spray, or cream so that you will feel only a small scratch and light pressure.

WHAT ARE THE POSSIBLE BENEFITS TO ME?

Nineteen out of every 20 children will have a negative screening test, so that 95% of those tested can be reassured that their risk of diabetes is no greater than the general population. The remaining one out of the 20, on the other hand, will have a positive result (two or more antibodies in the blood sample). Four of every ten people (40%) who have two or more antibodies may expect to become diabetic within five years. The clinical trial will be available to those who screen positive and, while we cannot know the results of the trial in advance, participation might prevent a further case of diabetes in your family. We also intend that the wider information learned from the study will help other children and young people who are at risk of developing diabetes in the future.

HOW WILL MY INFORMATION BE STORED?

All the information which we collect about you during the study will be kept confidential. Your blood sample will be labelled using a barcode and will not be directly identified. Your blood sample will be sent to our partner laboratory for antibody analysis. There may be small volumes of blood left over, and we will ask your permission to gift any residual blood to be stored and used in future medical research.
All your information will be stored securely and access will be limited to the research team. We will ask your permission to inform your GP that you have taken part in the study and that your antibody test results can be documented in your medical records. All study information will be kept for 15 years so that we can record if any children develop diabetes during or after their participation in the study and to allow us to make checks if there are any questions or queries at a later date.
We will publish and share our results with others in the field of diabetes. Your personal details will remain anonymous in any publications or presentation of the data.

FURTHER CONTACT

We will ask your permission to contact you with information about any future studies that may be of interest to you. You do not have to take part in these additional studies.

We will also ask for permission to be informed if you develop diabetes for up to 10 years beyond your participation in the study. This information is gathered from the Health Informatics Centre (HIC), University of Dundee or electronic hospital records. All information is anonymised. This will allow us to assess how effective our screening techniques are in predicting diabetes.

WILL WE BE TOLD ABOUT THE STUDY FINDINGS?

The trial will not be complete until the last child has been treated for five years. The results will then be made available on the study website.

WHAT IF THERE IS A PROBLEM OR SOMETHING GOES WRONG?

If you have a concern or a complaint about participating in the study, please speak first to our research nurse or the study doctor involved in your care. You can ask to speak to a senior member of the research team or the Complaints Officer at NHS your local Health Board/Trust. To do so, the study team will provide the contact details of the local Complaints Team.

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 against the NHS Health Board/Trust involved in the research or may have the right to make a claim for compensation against the University of Exeter, which is sponsoring the trial. Where you wish to make a claim, you should consider seeking independent legal advice, but you may have to pay for your legal costs.

WHO ARE CONDUCTING AND FUNDING THE STUDY?

The study team is led by Professor Terry Wilkin from the University of Exeter and Professor Stephen Greene from the University of Dundee. The study is sponsored by the University of Exeter, managed by the Tayside Clinical Trials Unit at the University of Dundee, and funded by the charity Juvenile Diabetes Research Foundation (JDRF).

WHO HAS REVIEWED THIS STUDY?

All research in the NHS is reviewed by an independent panel, called a Research Ethics Committee, to protect your interests. The East of Scotland Research Ethics Service (REC 1), which has responsibility for scrutinising all proposals for medical research on humans in the United Kingdom, has examined the proposal and has raised no objections from the point of view of medical ethics.

It is a requirement that your research documentation, together with any medical records, be made available for scrutiny by monitors from the University of Exeter or individuals appointed by the Sponsor whose role is to check that research is properly conducted and that the interests of those taking part are adequately protected.

WILL I RECEIVE PAYMENT FOR TAKING PART?

No, you will not receive payment for taking part in the study but we can cover reasonable travel expenses for your study visit.

WHERE CAN I FIND OUT MORE ABOUT RESEARCH?

If you wish to seek independent advice about taking part in the study you can contact Dr Michael Murphy, Clinical Reader at the Department of Biochemical Medicine, University of Dundee on 01382 383541 or m.j.murphy@dundee.ac.uk.

If you would like to find out more taking part in health research there are a number of organisations you can contact such as:
Scotland Children's Research Network CRN - www.scotcrn.org
Children's Research Network - www.crn.nihr.ac.uk/children
People in Research www.peopleinresearch.org
Health talk online www.healthtalkonline.org

Further Information

You can also find out more information about this study on the website www.adaptdiabetes.org

Chief Investigator: Professor Terry Wilkin
Contact Number: 07712 184547

Trial Manager: Dr Roberta Littleford
Contact Number: 01382 383991

Thank you for taking the time to read this information sheet, and for thinking about taking part.

Any Questions