

The Genetics of Type 1 Diabetes

Type 1 diabetes (or insulin dependent diabetes) is a common condition which normally develops during childhood and there is evidence that it may be affecting more people than it was ten years ago. Although there is a suspicion that this could relate to changes in the environment such as altered diets or different exposures to infections, diabetes only seems to develop in people who have inherited particular genes from their parents. Genes are the building blocks that we inherit from our parents that determine the colour of our hair and eyes and shape of body and in respect of diabetes, how we respond to changes in our environment which lead to the risk of diabetes. That is not to say that everybody who inherits these genes will develop diabetes but by understanding the genes which predispose to the condition, we may be able to understand further how it develops and in the future develop strategies to prevent the disease.

What the study involves

If you agree to participate in the study all that we would need to do is take a blood sample during your next clinic visit. The volume of blood taken would be around 20 mls (4 teaspoonfuls of blood), not dissimilar to the volume that you would give for many other tests. As someone with diabetes you will know that some discomfort can occur when you take blood from a vein but it is usually quite straightforward.

In addition, we will be asking you to fill in a simple questionnaire which documents your age, your age at diagnosis of diabetes, your sex and whether you have any diabetes

related complications. We will also be asking you whether there is somebody else in your family with a history of diabetes or other related conditions such as thyroid disease, rheumatoid arthritis, Addison's etc.

What will happen to the blood sample and the questionnaire?

The blood sample that you give will be labelled with a unique study number which could identify the hospital that you attend but it will not include your name or any other information which could identify your particular blood sample from all the others which are supplied to the laboratory in Cambridge. The questionnaire will be labelled with the same unique study number, and it will also be labelled with any local or national diabetes register numbers if you and your consultant are in agreement to this. The questionnaire, including the register number, will not be provided to the genetics laboratory in Cambridge, but will be kept separate and will only be used if you and your consultant agree to participate in any future studies related to other aspects of diabetes such as the development of complications.

Your blood sample, once donated, will be prepared in a way which makes the study of genes related diabetes possible over many years.

Will my DNA be used for anything else?

Your DNA will only be used for the analysis of genes relating to type 1 diabetes and associated conditions such as thyroid disease and it will only be made available to scientists studying these conditions. It is possible in the future that the DNA might be used to look at the genetics of diabetes related complications, and if your

consultant is collaborating on studies he/she would again ask for your consent and give you full information as to what the study involves before sending further information to the investigators.

What about insurance companies?

Participation in this study does not constitute a 'genetic test' as defined by insurance companies.

What will happen to the information collected?

Finding the genes that influence susceptibility to diabetes is likely to take at least 5 years. It will not be possible to feed back to you information concerning your particular genetic results, but we would promise to keep you informed through your local consultant and the local press as to how the DNA samples have contributed to our evolving understanding of the causes of type 1 diabetes and how this might lead to prevention in the future. It is always possible that from the 10,000 samples we wish to collect, it might be possible to identify a gene for potential treatment which could be patented for future prevention of diabetes, but this discovery would not arise out of the analysis of any individual sample, but rather in the analysis of all 10,000 bloods and the parallel collection of blood samples from subjects without diabetes.

Ultimately, if our aim is to prevent diabetes, information will be provided to pharmaceutical companies who would be the ones who would develop new drugs. Often at this stage a pharmaceutical company may provide financial assistance to do the research and in return would require the commercial rights to

benefits arising from discoveries. To allow potential collaborations to proceed, you are asked to waive any future claim to financial benefit through participation in the study. In this respect it should be noted that it is the whole collection of many thousands of DNA samples that is of value, and that each individual sample has in reality no commercial value on its own.

We intend that:

- Any significant discoveries or inventions are patented if possible, both to maximise the value of the research and to provide incentives for companies to develop the new therapies.
- A proportion of revenues from any industrial involvement is channelled back into research at universities and hospitals.

All records relating to the studies are treated in the same way as normal medical records and will be handled using the rules of the Data Protection act 1998. Details at:

www.dataprotection.gov.uk

or please ask us for a copy.

If I agree to join the study

If you are interested in joining the study, your consultant and the research nurse involved in the study would arrange a convenient time for the blood sample to be collected. Generally this would coincide with a clinic visit, but if there are particular problems with this, we may be able to arrange blood collection at other times which are more suitable to you. We would of course reimburse any travel expenses.

We are relying on your good will to participate for the benefit of all those who suffer from diabetes and particularly for those who may suffer in the future. Your involvement may help the current generation of sufferers and may offer radical new treatments for future generations. You are however under no obligation to participate in this study and if you decide not to take part it will not affect your normal diabetic treatment or management in any way, furthermore you can withdraw at any time without having to explain to anyone why you do not want to go forwards with the study.

If you gave blood, and at a later date decided to withdraw your participation in the study, we would respect your wishes and arrange for your sample to be destroyed.

Who should I talk to if I have any questions or concerns?

If you have any questions regarding this study, please contact us:

Consultant

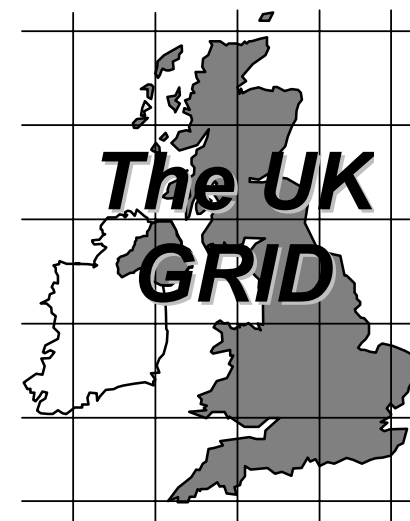
Tel: ??

Alternatively contact the Cambridge investigators by email: ukgrid@paed.cam.ac.uk or telephone: 01223 763130

On behalf of the Study Group for the Genetics of Type 1 diabetes, we would like to thank you for taking the time to consider participating in this important research programme.

CHILDHOOD ONSET DIABETES

Information leaflet for patients



Genetic Resource Investigating Diabetes
Juvenile Diabetes Research Foundation
Wellcome Trust

Address details here