Dear Parents & Parents to be,

In the first week of life, newborns are checked for treatable metabolic and hormonal disorders as part of the standard newborn screening tests. We would like to let you know about the option of another free test: a screening test to identify the risk of your child developing type 1 diabetes. The test is available as part of a research study being carried out by staff of the NHS and the University of Oxford. Several sites across Europe are also running similar studies. The test can be performed together with the standard newborn screening test where a few drops of blood from a vein or the baby’s heel are collected onto specimen collection paper. This extra test can be performed on the blood that is
already being taken as part of the standard newborn screening check. There are no extra needles or blood tests required for this test for risk of diabetes, and taking part is voluntary.

Why are we interested in screening for diabetes risk?

Type 1 diabetes is a relatively common metabolic disease in children and adolescents. It is caused by insulin deficiency. Insulin helps transport glucose from blood into cells. Children with type 1 diabetes require life-long treatment with insulin. One difficult aspect of type 1 diabetes is that it is usually only recognised when the person affected already has serious and sometimes even life-threatening symptoms. When children with an increased risk of diabetes are identified at an early stage, these complications can be prevented.

Type 1 diabetes primarily occurs in individuals who have certain high risk genes. Most children who have these high risk genes and develop diabetes do not have any relatives with diabetes. In other words, the disease can affect anyone. Our screening test checks to see if your child carries high risk genes for type 1 diabetes. Approximately 1% or 10 out of every 1,000 children have high risk genes for type 1 diabetes. If your child has these high risk genes, their risk of developing diabetes is approximately 10%.

This is the only screening test available for determining which children may develop type 1
diabetes. It will capture approximately 25 out of every 100 children who do so.

**What do I need to do as part of this study?**

If you would like to have this additional test performed on your child’s routine blood sample, we would ask you to sign a consent form and to provide us with your name, contact details and NHS number. A local database will store this information but we would not share this outside the study team. We would also ask you about the family history of type 1 diabetes. Staff from the research team may need to check your child’s NHS records or contact your GP/Health Visitor, but no one else would be told about your involvement in the study.

**Will my child’s taking part in the study be kept confidential?**

The data that we obtain from you and your child will be strictly confidential. You, your child and your child’s blood test will be assigned a unique study number for our database. This number, along with your child’s gender, date of birth, date of screening test and family history of diabetes will be shared with our study partners, but they will not know your, or your child’s name. Our partners include study teams in Sweden, Poland, Belgium and various sites across Germany. The lead team are located in Munich, Germany. Once the study has ended, all identifiable data will be deleted.
Responsible members of the University of Oxford and the relevant NHS Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations. Your child’s blood sample will be stored securely and analysed in a laboratory in the UK. Once analysed, any remaining sample will be destroyed.

**What happens if the test result is normal?**

You will not be contacted if the test result is normal. If you have not heard from the study team within 16 weeks of the test, you can assume that your child does not have high risk genes for type 1 diabetes. If you are still unsure, you can phone us to ask for the test result on (01865) 221107. Your contact details will be held until the end of the study when they will be deleted from our database.

**What happens if the test finds that your child has high-risk genes?**

If your child has high risk genes for type 1 diabetes, the Oxford Vaccine Group, who are part of the study team, will check your child’s health status via their medical records prior to contacting you. We will contact you and your GP within 16 weeks of the test to provide you with a booklet explaining the test results, and invite you to discuss the implications of this. Most children with high risk genes will never go on to develop diabetes. We will give you detailed advice and training on how to recognise the symptoms of diabetes, so that if your child does develop these then you can seek appropriate help.
You will also be invited to take part in a new study called POInT (Primary Oral Insulin Trial). POInT examines whether the development of type 1 diabetes can be prevented in children with an increased risk of type 1 diabetes through preventive treatment with insulin. In POInT, the insulin is given orally (via mouth) as a powder and is not used to lower blood glucose levels. Instead, it is designed to train the immune system to lessen the risk of type 1 diabetes.

What happens to my and my child’s data?

We will be using information collected from you, your child, and your and your child’s medical records in order to undertake this study. Research is a task that we perform in the public interest. The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will only use the minimum personally-identifiable information possible. We will keep identifiable information about you and your child until the end of the study, when it will be disposed of. We will store the de-identifiable research data and any research documents with personal information, such as the completed consent forms, securely at the University of Oxford for 21 years from when the last study participant is recruited.

Your rights to access, change, or move your or your child’s personal information may be limited, as we
need to manage your and your child’s information in specific ways in order for the research to be reliable and accurate. You can find out more about how we use your information by contacting INGR1D@wrh.ox.ac.uk

The de-identifiable data from this study will be included in a worldwide database to help the research community tackle diabetes in future (see www.gppad.org for more details). Data access will be protected by password and via a secure, encrypted connection in all cases. Only members of the research consortium will be able to access the data.

How will I receive a copy of my questionnaire and consent form?

As consent to this study is primarily given electronically, a copy of your questionnaire and consent form can be emailed to an address you provide. This document will contain the personal information you provide in the questionnaire, such as your NHS number, your family history of type 1 diabetes, and your contact details. Although every care is taken to ensure that the emailing of consent forms is secure, this cannot be guaranteed. In view of this, please inform a member of the study team if you would instead prefer to receive a paper copy of the consent form.

Under what circumstances would my child’s blood sample not be analysed as part of the INGR1D study?
At present, only newborn bloodspot samples processed at the John Radcliffe Hospital in Oxford can have the INGR1D screening performed on them. Most samples taken in the Thames Valley region will be processed at this site and every care is taken to ensure only women living in specific geographic areas are recruited to the study. However, it may be that you are out of area, either in planned or unplanned circumstances (for example, if you move house or have your baby in a different part of the UK), when the newborn bloodspot screening is performed. In this case, your child’s sample would not be processed in Oxford and you would be withdrawn from the study. We would inform you if this were the case.

**What if I wish to withdraw from the study?**

You are free to withdraw at any time. You do not have to provide a reason, and this will not affect your or your child’s medical care. If you wish to withdraw please email us at INGR1D@wrh.ox.ac.uk.

**What if there is a problem?**

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the study team either on (01865) 221107 or INGR1D@wrh.ox.ac.uk or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on, 01865 (6)16480 or email the head of CTRG at ctrg@admin.ox.ac.uk.
Who has reviewed the study?

This study has been reviewed and given favourable opinion by Hampshire A Research Ethics Committee.

Contact us

The INGR1D team:

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Partners:

The INGR1D study is part of

GPPAD

GLOBAL PLATFORM FOR THE PREVENTION OF AUTOIMMUNE DIABETES