

If you would like more information or assistance, please contact us on (01865) 221107

### 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](mailto: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](mailto:INGR1D@wrh.ox.ac.uk) or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224, or the head of CTRG, email [ctrq@admin.ox.ac.uk](mailto:ctrq@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:

OSPREA

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#### Partners:



Oxford Biomedical Research Centre  
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# INGR1D



## INvestigating Genetic Risk for type 1 Diabetes

### Information on newborn screening for the risk of developing type 1 diabetes

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 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. In our screening test we would check to see if your child has 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%.

## 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/your child's NHS records or contact your GP, 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 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. The anonymised data from this study will be included in a worldwide database to help the research community tackle diabetes in future (see [www.gppad.org](http://www.gppad.org) for more details).

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 (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.