Freder1k study in Saxony: Early detection of the risk of developing type 1 diabetes

Declaration of consent to carry out a screening test for the risk of diabetes in newborns – Saxony Dresden Screening Centre

Child's first name: _____

Child's surname:_____

Postal code/town or city:_____

I consent to my child being screened for the disease stated as part of the newborn screening for diabetes as well as the transmission of data to the screening laboratory at the Institute of Clinical Chemistry and Laboratory Medicine, Carl Gustav Carus University Hospital Dresden, Technische Universität Dresden, the Institute of Diabetes Research, Helmholtz Zentrum München and the Center for Regenerative Therapies, Technische Universität Dresden, and the Department of Paediatrics, Carl Gustav Carus University Hospital, Technische Universität Dresden. Mr/Ms/Dr/Professor_____ explained the procedure and the collection of blood required, as well as the associated risks and limitations, and I was able to ask questions. In particular, it was pointed out to me that in this study an abnormal result indicates an increased risk, but is not a diagnosis. I hereby consent to my child's data being used in pseudonymous form, i.e. without identification by name, for scientific purposes.

Medical confidentiality and data protection requirements will be upheld when transmitting data to the screening laboratory, the Institute of Diabetes Research, Helmholtz Zentrum München, the Center for Regenerative Therapies, Technische Universität Dresden, Department of Paediatrics, Carl Gustav Carus University Hospital, Technische Universität Dresden. Personal identification of the data cannot be reconstructed by third parties.

Participation in the newborn screening for diabetes is voluntary. My consent only applies to the diseases stated.

The specimen collection papers with the blood samples are only stored until the result of the test is available. They are then destroyed.

_____
Date and signature of at least one parent or guardian

_____
Location/date

Contact us

Professor Ezio Bonifacio
Center for Regenerative Therapies,
Technische Universität Dresden,
Fetscherstrasse 105, 01307 Dresden, Germany

Phone: 0800 72 45 148 (freephone)
Email: diabetesstudie.crtd@tu-dresden.de
Web: www.gppad.org

Partners in GPPAD

Institute of Diabetes Research, Helmholtz Zentrum München

Center for Regenerative Therapies, Technische Universität Dresden

Department of Paediatrics, Carl Gustav Carus University Hospital Dresden

Institute of Clinical Chemistry and Laboratory Medicine Screening Laboratory, Carl Gustav Carus University Hospital Dresden

Department of Paediatrics, University Hospital Leipzig

Institute of Laboratory Medicine, Clinical Chemistry and Molecular Diagnostics (ILM), University Hospital Leipzig

Freder1k

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>> Information on newborn screening in Saxony for the risk of developing type 1 diabetes

Dear parents,

Between the second and third day of life, newborns are checked for treatable metabolic and hormonal disorders as part of the standard newborn screening tests. In the following, we would like to let you know about another free test: **a screening test to identify the risk of developing type 1 diabetes**. The test is carried out by your gynaecologist or paediatrician at the hospital and can be performed together with the standard newborn screening. A few drops of blood from a vein or the baby's heel are collected onto specimen collection paper.

Partners

HelmholtzZentrum münchen
Deutsches Forschungszentrum für Gesundheit und Umwelt

CRTD Center for Regenerative Therapies TU Dresden

TECHNISCHE UNIVERSITÄT DRESDEN

UNIVERSITÄT LEIPZIG

What diseases are included in the screening test?

The risk of developing the following diseases is analysed in the screening test:

- Type 1 diabetes
- Neonatal diabetes mellitus

Why should infants be screened for diabetes?

Type 1 diabetes is a relatively common metabolic disease in children and adolescents. It is caused by insulin deficiency. Insulin helps transport glucose from your blood into your cells. Children with type 1 diabetes require lifelong 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 check to see if your child has high-risk genes for type 1 diabetes.

Approximately 3% or 30 out of every 1,000 children have high-risk genes for type 1 diabetes.

Neonatal diabetes mellitus (NDM) is a rare form of diabetes. It occurs in about one in 300,000 infants within the first six months of life. The early detection and treatment of NDM is important for normal development of newborns. In our screening test we identify whether your child has elevated blood glucose levels.

If your child has elevated blood glucose levels, your paediatrician will contact you and arrange other tests to identify whether your child has NDM.

What happens if the test result is normal?

You will not be contacted if the test result is normal. So this means that no news is good news. If you have not heard from your paediatrician or the Center for Regenerative Therapies at the Technische Universität Dresden within 12 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 (freephone: 0800 72 45 148).

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

If your child has high-risk genes for type 1 diabetes, your paediatrician or the Center for Regenerative Therapies at the Technische Universität Dresden will contact you within 12 weeks of the test. You will be invited to bring your child for additional tests at six months, two years and four years of age. These follow-up tests will show if your child has an early stage of type 1 diabetes. The earlier the disease is detected, the sooner it can be treated. For every 100 children with high-risk genes, about five of these children will develop an early stage of type 1 diabetes by their fourth birthday.

What does a diagnosis of 'early stage of type 1 diabetes' mean?

Most children who are at an early stage of the disease have no or very few symptoms. They feel perfectly healthy and there is no risk to their health at this time. We will discuss the next steps and support you through this situation. You will be given detailed advice and training and an individual care plan for your child. Regular check-ups will be carried out to determine if and when your child should begin insulin treatment in the event of type 1 diabetes.

Being diagnosed with an early stage of type 1 diabetes also means that you and your child will have the opportunity to participate in studies that aim to prevent the progression of the disease. We will support you with advice and assistance during this phase of early type 1 diabetes.

If you need information or assistance, you can call us on our freephone number: 0800 72 45 148.

The Frederlk study is a project by

GPPAD
GLOBAL PLATFORM FOR THE PREVENTION OF AUTOIMMUNE DIABETES

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