

Fr1da-Studie in Bayern

Early diagnosis and care of type 1 diabetes

Informed consent for participation

If you would like to participate in the investigation with your child, we need your written consent. You can withdraw participation in the study at any time without stating a reason. If you decide to stop participating, you should contact the Institute of Diabetes Research, Helmholtz Munich (Tel. 0800 - 464 88 35).



The well-known children's song duo Margit Sarholz & Werner Meier are Fr1da ambassadors.



How is the confidentiality of your data guaranteed?

The personal data of your child can only be viewed by employees of the Institute of Diabetes Research, Helmholtz Munich and by your paediatrician. Your child's test results and all other data collected during the investigation are stored electronically, used only for scientific and statistical purposes and are never used in connection with your name or the name of your child. Your data will be pseudonymised, which means that every child and every biological sample is assigned a code number by the staff of the Institute of Diabetes Research, Helmholtz Munich. No personal reference can be restored by third parties.

Information for study participants regarding data protection

Controller responsible for data processing:
Helmholtz Munich, Ingolstädter Landstrasse 1, 85764 Neuherberg

Data protection officer:
Werner Bergheim, Helmholtz Munich, Ingolstädter Landstrasse 1, 85764 Neuherberg, Email: datenschutz@helmholtz-munich.de

Data protection manager of the controller:
Manja Jolink, Institute of Diabetes Research, Helmholtz Munich, Ingolstädter Landstrasse 1, 85764 Neuherberg

Responsible data protection supervisory authority:
The Federal Commissioner for Data Protection and Freedom of Information
Husarenstraße 30
53117 Bonn
Telephone: 0228 - 99 77 99 - 0
Email: poststelle@bfdi.bund.de

You have the possibility at any time to obtain information about your personal data and, if necessary, to request their correction or deletion. You have the right to complain if your request is not followed up.

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Scientific management



Univ.-Prof. Dr. med. Anette-G. Ziegler

Director of the Institute of Diabetes Research, Helmholtz Munich;
Chair of Diabetes and Gestational Diabetes, University Hospital rechts der Isar, Technical University of Munich

HELMHOLTZ MUNICH



Contact

If you have any further questions about participation, we will be pleased to answer them.

Institute of Diabetes Research
Helmholtz Munich
Heidemannstraße 1
80939 Munich

Tel.: 0800 - 464 88 35 (free)

E-Mail: diabetes.frueherkennung@helmholtz-munich.de

Website: www.fr1da-studie.de

Supported by



Information regarding participation in the study

Dear parents,

more and more children are developing type 1 diabetes. In the following we would like to inform you about the project "Early diagnosis and care of type 1 diabetes". By examining a few drops of blood, we can detect whether your child has an early stage of type 1 diabetes.

If this is the case, the disease can be treated in an optimal manner early on. Participation in the study is voluntary and free of charge for you. It requires the written consent of the parents.

The study is conducted by the Helmholtz Munich in cooperation with the Berufsverband der Kinder- und Jugendärzte e. V., Landesverband Bayern (Professional association of paediatricians, Bavarian State Association) and Paed-Netz Bayern e. V..

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What is type 1 diabetes?

Type 1 diabetes is an autoimmune disease. This means that the body's immune system, which primarily serves to ward off germs, instead targets and destroys the insulin-producing cells of the pancreas.

As a result, there is no insulin production. The hormone insulin is responsible for transporting sugar from the blood into cells that need it to generate energy. If there is a lack of insulin, the sugar accumulates in the blood. Those affected must therefore inject insulin to prevent the health problems caused by high blood sugar levels.

What does type 1 diabetes early detection mean?

Your child's blood will be tested for islet autoantibodies. Islet autoantibodies are signs of inflammation of the insulin-producing cells of the pancreas; they can be detected in the blood years before there is an insulin deficiency and an increase in the blood sugar level. The detection of islet autoantibodies indicates type 1 diabetes. About 0.3 percent or 3 out of 1,000 children examined have islet autoantibodies in their blood.

What are the benefits of participating in a type 1 diabetes early detection examination?

Most people who suffer from type 1 diabetes develop the disease in childhood. If no islet autoantibodies are found in your child's blood during this medical examination, then the likelihood is very low that he or she will develop type 1 diabetes later. If islet autoantibodies are found in your child's blood, he

or she can be cared for and treated in an optimal manner early on. This can prevent life-threatening hypoglycaemia, which can occur relatively quickly and without warning. We will inform and advise affected children and their parents in detail.

There are also trials for new treatments to prevent the disease from progressing. We will offer interested families the opportunity to participate in such studies.

How does the examination work and what is examined?

The examination is offered to children in the age range of 2-10 years either as part of the respective preventive check-up (U7, U7a, U8, U9, U10, U11) or at any other visit to a paediatrician. The examination is also available to the 1-21 year-old relatives of people with type 1 diabetes.

The detection of the islet auto-antibodies is carried out using a few drops of blood, which are obtained by a small prick in the finger. The blood sample is sent to the laboratory of the Institute of Diabetes Research, Helmholtz Munich.

There, it is examined using speci-



al and very sensitive test methods. Taking blood from a finger does not pose any danger or risk to your child. It could cause a small bruise, swelling, or infection. However, the risk of infection is very low.

The child looks healthy. Should he or she still be tested?

Yes! Most children who develop type 1 diabetes show no symptoms in the early stage of the disease. The study enables the detection of type 1 diabetes at this early stage by means of a blood test. Monitoring blood sugar early allows for the future prevention of serious health problems.

What happens to the test result?

Normal test results are not communicated. Therefore, this means for you: No news = good news. If you have not received any contrary information from your paediatrician practice within 8 weeks of the blood extraction, you can expect a normal test result. If you are still unsure, you can ask your paediatrician/physician about the test result.

The practice that performed the blood draw will be informed of a conspicuous test result. If necessary, your doctor will contact you to verify the conspicuous test result in a second blood sample.

If islet autoantibodies are detected during the measurement, the diagnosis "Early stage of type 1 diabetes" is determined. In this case, you will be informed immediately and invited to a check-up, as well as a detailed advice and training session.

What does the diagnosis mean: Early stage of type 1 diabetes?

Most children with islet autoantibodies in the blood are at an early stage of type 1 diabetes and have no symptoms. They feel perfectly healthy and have no current health risk. We will discuss the further procedure with the parents affected and their paediatrician and will support them in this situation as best as possible. The child's metabolism will be carefully monitored regularly. The parents receive detailed advice and training as well as an individual care plan for their child. Regular check-ups determine when insulin treatment should be started.

An estimated 75 percent of children with positive islet autoantibodies will need insulin treatment within ten years. For this reason, the parents are gradually familiarised with insulin therapy and referred to a paediatric practice or children's clinic specialising in type 1 diabetes.

During this phase of early-stage type 1 diabetes, we support the families affected with advice and action. If you need information or support, you can contact our free telephone hotline with your questions and concerns: 0800 - 464 88 35. We will also connect you to relevant experts.