



Information for study participants regarding data protection

The legal basis for data processing is your consent (Article 9 Section 2a und Article 6 Section 1a of the European General Data Protection Regulation).

Controller responsible for data processing

Helmholtz Munich
Deutsches Forschungszentrum für Gesundheit und Umwelt (GmbH)
Ingolstädter Landstrasse 1, 85764 Neuherberg

Data protection officer

Helmholtz Munich
Deutsches Forschungszentrum für Gesundheit und Umwelt (GmbH)
Ingolstädter Landstrasse 1, 85764 Neuherberg,
E-Mail: datenschutz@helmholtz-munich.de

Responsible data protection supervisory authority

The Federal Commission for Data Protection and Freedom of Information
Husarenstraße 30, 53117 Bonn
Telefon: +49 (0)228-997799-0,
E-Mail: poststelle@bfdi.bund.de

You have the possibility at any time to obtain information about your child's personal data (including, upon request, a free copy), and if necessary, to request its correction, deletion, or restriction of processing. You also have the right to receive the data you have provided in a standardized electronic format or to have it transmitted to a body you specify (Right to Data Portability).

How is the confidentiality of your data guaranteed?

Your personal data / the data of your child will be encrypted, i.e., all data that can be used to identify you or your child (name, date of birth, address etc.) will be replaced by a code.

Personally identifiable data can only be viewed by employees of the Institute for Diabetes Research, Helmholtz Munich, and will be stored separately from the encrypted data (examination results and medical data). This largely prevents unauthorized people from identifying you or your child. Data that can be used to identify you or your child will not be transferred to researchers or other third parties, insurance companies or employers. The encrypted data (examination results and medical data) of your child will also be stored at Helmholtz Munich. Helmholtz Munich can use your encrypted data for scientific purposes and can share these data with external research partners such as universities, hospitals, and research companies. In some cases, your encrypted data may also be linked to medical data in other databases, provided that the legal requirements for this are met. Data released to researchers may only be used and shared for scientific and health-related research.

Scientific and health related research includes basic research, applied research, and privately and/or publicly financed research with the goal of developing new methods for diagnosis, therapy, and prevention of health problems. The encrypted data of your child could additionally be transferred to recipients in countries outside the EU. In such countries, a lower level of data protection may apply. To ensure the protection and confidentiality of the encrypted data, both the data provider and the data recipient implement appropriate security measures. All data is stored only as long as permitted by law and is deleted after the statutory retention periods have expired.

Encrypted data from children with an early stage of type 1 diabetes will be included in a European registry (pre-T1D Register <https://www.pre-t1d-registry.eu/>). This registry collects data about islet autoantibody status and blood sugar measurements (for example, during glucose tolerance tests), HbA1c, and information about metabolic parameters during clinical diabetes manifestation. The registry will be managed by Helmholtz Munich.

Contact Us

If you have additional questions about participation, we will gladly answer them for you in a personal conversation.



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www.fr1da-studie.de

Scientific management:

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

HELMHOLTZ
MUNICH



In cooperation with:



Berufsverband der
Kinder- und Jugendärzt*innen



European action for the Diagnosis of Early
Non-clinical Type 1 diabetes For disease interception

Research supported by:



Typ-1-Diabetes: Früh erkennen – Früh gut behandeln

Information about participation in the Fr1da 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 Jugendärzt*innen e.V. (Professional association of pediatricians).

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?

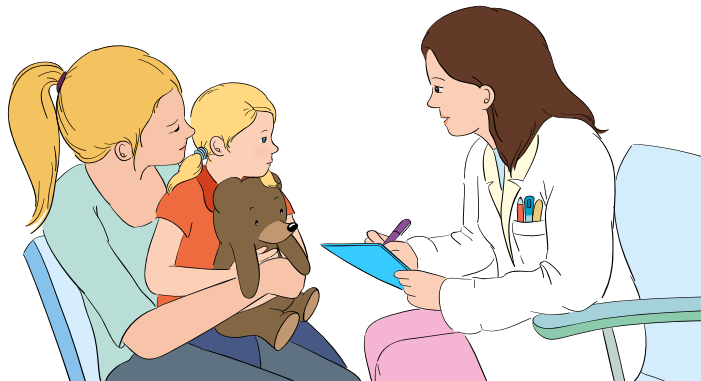
Your child's blood will be tested for islet autoantibodies. Islet autoantibodies are signs of inflammation of the insulin-producing cells of the pancreas; they can be detected in the blood years before there is an insulin deficiency or any sign of illness. The detection of islet autoantibodies indicates early-stage 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 are affected by type 1 diabetes develop the disease in childhood. If no islet autoantibodies are found in your child's blood during this medical examination, testing for islet autoantibodies can be repeated a second time. If after all tests, no islet autoantibodies are detected, the likelihood is very low that your child will develop type 1 diabetes later.

If islet autoantibodies are found in your child's blood, your child has early-stage type 1 diabetes, which can be cared for and treated in an optimal manner early on. This can prevent life-threatening hyperglycemia, which can occur relatively quickly and without warning. We will inform and advise affected children and parents in detail.

There are also new treatment approaches available, including immunotherapies, which can slow the progression of the disease. People with early-stage type 1 diabetes have the opportunity to participate in such therapies. We would like to enable interested families to participate in such therapy programs.



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 pediatrician. Here, we recommend that the early-stage type 1 diabetes examination be conducted at two time points: at 3 years of age (U7a) and at 7 years of age (U10).

We additionally offer the examination to relatives of people with type 1 diabetes who are between 1 and 21 years old. We also recommend two tests in the case of relatives of people with type 1 diabetes.

The detection of the islet autoantibodies 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 special 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. That means for you, no news is good news. If you have not received any information to the contrary from your pediatrician within 8 weeks of the blood extraction, you can assume a normal test result. If you are still unsure, you can ask your pediatrician 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 "Early-stage type 1 diabetes" mean?

Most children with islet autoantibodies in the blood are at an early stage of type 1 diabetes and have no signs of illness. They feel perfectly healthy and have no current health risk.

We will discuss further procedures with the parents affected and their pediatrician and will support them in this situation as best as possible. The child's blood sugar 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 early-stage type 1 diabetes will need insulin treatment within ten years. For this reason, the parents are gradually familiarized with insulin therapy and referred to a pediatric practice or children's clinic specializing in type 1 diabetes. We provide advice and support to affected families and children with early-stage type 1 diabetes.

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 with relevant experts.

Fr1da Study: 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).

Further information about the Fr1da Study can be found on our website:
www.fr1da-studie.de



Scan the QR code to access the website.

