

What is the Pre-POINT study?

The Pre-POINT study is the first study that offers an immunization-like treatment to delay or even prevent autoimmunity and type 1 diabetes.

The preventative treatment with insulin is intended to stop the development of diabetes auto-antibodies in children with high genetic risk. Diabetes auto-antibodies are the first markers of the autoimmune process prior to the Diabetes disease.

The child may take the insulin by mouth on a daily basis. Insulin given in these ways does **NOT** lower blood glucose, but it is supposed to influence the immune system, similar to an immunization.

Children in the study will be asked to take the treatment for between 3 and 18 months. The aim of the study is to find the most appropriate dose and type of administration of the insulin to do this.

After completion of the Pre-POINT study we expect to start the POINT study. In the POINT study we will investigate the protective effect of an insulin vaccination over a longer period of time and whether we are able to prevent the onset of the Diabetes. Children who participate in Pre-POINT will also be able to take part in POINT, if they choose.

Children aged between 2 and 7 years can participate in the Pre-POINT study if they have a high genetic risk (up to 50%) to develop Diabetes, and are Diabetes autoantibody. Having a very high genetic risk for developing Diabetes means they have at least a multiple first degree family history of Type 1 Diabetes and have also susceptible genotypes at the major Diabetes-related genes.

The Pre-POINT study is supported by the German Federal Ministry of Education and Research (BMBF) and the Juvenile Diabetes Research Foundation (JDRF) in the USA.

Where will the study be carried out?

Pre-POINT is an international study. Dr. Georgeanna Klingensmith of the Barbara Davis Center for Childhood Diabetes at the University of Colorado Denver is the primary investigator for the USA study center. There are other study centers in Austria, Canada, Italy, Germany and Great Britain.

Free Diabetes Risk Screening

To find children with a high risk to develop Diabetes, we initially carry out a first examination to assess your child's Diabetes risk (Screening). Screening can begin when your child is 18 months old and prior to their 7th birthday.

All children from Germany, Austria, Italy, the UK, the USA and Canada can participate if they

- are between 2 and 7 years of age
- and**
- at least one brother or sister or both parents have type 1 Diabetes

How can you participate?

Please send us the questionnaire with your details (the white section on the right) by mail. We will be happy to send you information about the screening and the necessary study materials.

Data privacy

Your personal details will be kept confidential and will only be seen by the research teams in our study centers. We will store the details in the form in which you sent them and in an electronic database during the study and will destroy or delete them when the study has finished. We need the information in order to contact you and check the conditions for the screening, and also for statistical and scientific purpose.

Information to data privacy

The provided contact data and data of your child can only be reviewed by the staff of the clinical centers. They have to respect data privacy by law. We need this information to clarify the screening conditions and to contact you in case of a participation. The data will be saved in hardcopy and electronically and will be destroyed or deleted when the study has finished.

Consent form

I agree with the stated data ascertainment, data handling and data utilization.

Date and signature of one parent

First name and family name of the mother

First name and family name of the father

Birth date of the mother / Birth date of the father

Street

Zip Code/ City

Tel. number

Information of the tested child

First name of the child

Family name

Date of Birth

gender: male female

Information on the family of the child

In the family of the child, are there one or more relatives affected by type 1 diabetes?
(please do not declare gestational Diabetes and Type 2 Diabetes!)

yes no

If yes, who:

mother of the child

Father of the child

Brother / Sister of the child

further Brothers / Sisters of the child

_____ of the child

Fill out the questionnaire and remove it from the flyer and send the consent form back to:

Maria King
Barbara Davis Center
1775 Aurora Ct, Mailstop F527
Aurora, CO 80045



You can keep the information flyer (green information sheet) for your documents!

Why should your child take part?

- There is currently no established treatment for children at high genetic risk of developing diabetes but the treatment during the Pre-POINT study might possibly prevent the onset of the disease.
- The treatment and the examinations during the study are free.
- We will examine your child at regular intervals. Thus, if your child develops diabetes, we will be able to detect the onset of diabetes before any of the typical symptoms show, which will reduce the risk of complications.
- In the event that your child develops diabetes during the Pre-POINT study we will be able to provide you with information about other studies that could affect the course of the disease.

For further questions the Pre-POINT team would be glad to assist you.

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Vaccination against type 1 diabetes

A new treatment in children with a very high diabetes risk might potentially prevent diabetes development

Pre-Point 