

POInT Study

>> Prevention of Type 1 Diabetes



Please do not hesitate to contact us via our freephone number or at the following address if you have any questions:

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What is the POInT study?

Type 1 diabetes is an autoimmune disease. This means that the immune system, which primarily serves to defend the body against germs, attacks and destroys the insulin-producing cells (beta cells) in the islets of Langerhans in the pancreas.

The aim of the POInT (Primary Oral Insulin Trial) study is to prevent the destruction of the insulin-producing cells of the pancreas in children with an increased risk of type 1 diabetes and therefore prevent the development of type 1 diabetes.

The presence of autoantibodies to the cells that produce insulin is an indication of the inflammation and destruction of the insulin-producing cells of the pancreas. The POInT study aims to prevent these autoantibodies from developing by training the immune system, so that this mistaken immune reaction does not occur. This training is carried out by giving a daily dose of insulin powder together with a meal. The body's own insulin is often the first target of the mistaken immune reaction, which leads to type 1 diabetes. Through exposure via the mucous membranes of the mouth and the digestive tract, the aim of the insulin powder is to train the immune system to tolerate the body's own insulin, thereby preventing the destructive immune reaction. Unlike insulin that is injected, the insulin powder does not serve to lower the blood glucose level.

Why should my child participate in the POInT study?

In children with high-risk genes for type 1 diabetes, a mistaken reaction by the immune system against the insulin-producing beta cells in the pancreas is most likely to occur

between the ages of six months and three years. This was shown by analysis of the data from the German BABYDIAB study and the international TEDDY study. This is why it is particularly advisable to take preventive steps to train the immune system in the first few years of life, before any symptoms of the destruction of the insulin-producing cells of the pancreas occur.

In the best-case scenario, the development of type 1 diabetes can be avoided through this early training.

If your daughter or son participates in the POInT study, she or he will be examined regularly. If your child does develop symptoms of the destruction of the insulin-producing cells, this can be identified at an early stage.

There is no charge for the treatment and investigations carried out as part of the POInT study.

What happens in the POInT study?

Children aged between 4 and 7 months can participate in the POInT study to prevent type 1 diabetes.

At the beginning of the study, you and your child will be invited to regular examinations at intervals of 2 to 4 months until your daughter or son is 18 months old. Your child will then be examined every 6 months until he or she is 3 years old.

During this time, the study participants are given the contents of a capsule of powder each day. They take the powder together with food (e.g. stirred into baby food, yoghurt or milk). Half of the participants are given insulin powder, and the other half are given a placebo (an inactive substance).

It is a double-blind study, which means that neither the study participants nor the doctors know which capsules contain insulin and which contain the placebo.

The treatment finishes when your child turns 3 years of age. Afterwards, further physical examinations and blood tests are carried out by our doctors at the study centre every 6 months. The longest possible period over which the follow-up visits will take place is until your child is 7.5 years old.

Who can participate in the POInT study?

Your child can be included in the POInT study if:

- he or she is between 4 and 7 months old;
- it has been identified that he or she has a high-risk for type 1 diabetes by genetic typing;
- he or she has already begun to eat small quantities of baby food.