

# Insulin vaccine for type 1 diabetes undergoes second trial

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A vaccination against type 1 diabetes will soon also be available to young children: the Pre-POINTearly vaccination study will involve children between the ages of six months and two years from across Germany who have a first-degree relative with type 1 diabetes. In the preceding Pre-POINT study a positive immune response was triggered in children aged between two and seven years with the aid of powdered insulin. The follow-up Pre-POINTearly study will now test whether this effect can be confirmed by giving very young children oral insulin, and whether type 1 diabetes can be prevented in the long term.

The insulin vaccination trial is a prime example of the excellent cooperation between universities and research institutes. Participants in the study are the Institute of Diabetes Research at the Helmholtz Zentrum München, the Paul Langerhans Institute Dresden at the Technische Universität Dresden, the German Center for Diabetes Research (DZD), the Technical University of Munich (TUM) and the Ludwig Maximilians University of Munich (LMU).

The new Pre-POINTearly vaccination study will treat children between the ages of six months and two years who carry a genetic risk of developing type 1 diabetes or have a family history of the disease, but who have not yet developed an autoimmune response. As in the preceding Pre-POINT study, the participants will take the insulin in powder form with their food every day for twelve months. The daily dose will be gradually increased from 7.5 mg to 67.5 mg. Medical examinations will be conducted at three-month intervals in order to

monitor the general health of the participants. In the preceding study, oral insulin was shown to be well tolerated and safe. Hypoglycemia or other adverse effects such as allergies did not occur.

## Why oral insulin as a vaccine?

When insulin is given orally, it is absorbed through the mucous membranes of the mouth and the intestines, and is split into smaller components during the digestive process. That is why oral insulin – in contrast to insulin that is injected – has no influence whatsoever on blood sugar levels. Instead it acts like a vaccine that trains the immune system. "The [autoimmune response](#) that causes type 1 [diabetes](#) in childhood is often initially directed at the insulin," explains Prof. Anette-Gabriele Ziegler, Director of the Institute of Diabetes Research. The aim of the Pre-POINTearly study is therefore to build up immune tolerance to insulin and thus block the autoimmune process." It is hoped that insulin in powder form will stimulate the growth of protective immune cells and thus prevent the destruction of beta cells.

Provided by Helmholtz Association of German Research Centres

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