

Type 1 diabetes: First hurdle taken on the way to an insulin vaccine

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Scientists from the DFG Center for Regenerative Therapies Dresden, TU Dresden and the Institut für Diabetesforschung, Helmholtz Zentrum München, together with researchers from Vienna, Bristol and Denver (USA) have successfully completed the first step in development of an insulin vaccine to prevent type 1 diabetes.

As reported by these diabetes researchers in the current edition of the renowned scientific journal *JAMA*, evaluations of the international Pre-POINT study point to a positive [immune response](#) in persons at risk for the disease who were given oral doses of [insulin](#). Adverse reactions such as hypoglycaemia were not observed. The objective of the next phase of testing will be to determine whether an insulin vaccine can prevent the outbreak of the disease over the longer term.

Children with [type 1 diabetes](#) require several [insulin injections](#) every day of their lives. This is because the body's own [immune system](#) destroys the beta cells in the pancreas - the cells that produce insulin. This is a process that starts early. Instead of ignoring proteins such as insulin, the immune defences see insulin and other proteins in the cells as foreign and mobilize immune cells to destroy the [beta cells](#). Normally, the immune system develops an immune tolerance to the body's own proteins during the first years of life, thus preventing this type of autoimmune response. This tolerance includes the training of immune cells that prevent destruction of the body's own cells. The aim of the insulin vaccine is to help "train" this positive preventive immune response.

In the Pre-POINT study, children at high risk for developing type 1 diabetes in Germany, Austria, the United States and the United Kingdom were treated with oral insulin once daily over periods averaging half a year. The control group was given only a placebo with no effect. The active substance group ingested the insulin in powder form together with food at varying dosage levels that were increased in the course of the study. In the highest dosage (67.5 mg), the insulin powder then induced the desired immune response. Professor Ezio Bonifacio from the Center for Regenerative Therapies, who acted as the Principal Investigator for the study, commented on the results as follow: "...we were pleased to see that there were no unwanted side effects and thus far only signs that we could mimic what normally happens in children who don't get type 1 diabetes." Since insulin in this dosage form is broken down in the stomach it did not influence blood glucose levels. "...we believe that most of the response is happening while insulin is still in the mouth", Bonifacio added.

In the opinion of Prof. Anette-Gabriele Ziegler from the Institut für Diabetesforschung, which also contributed to the study, the unique thing about this double-blind study is that the insulin was administered as a prophylactic vaccine to the children before they had developed an autoimmune response - that is before they produced autoantibodies. Ziegler continued: "This is a revolutionary way to prevent type 1 diabetes, but it is quite logical that if the body's immune system doesn't learn how to make the protective responses by itself, we need to give it a little help."

The JDRF (Juvenile Diabetes Research Foundation) in the US, which provided supportive funding for the project, assessed the study results in a positive light: "The JDRF is very encouraged by the results of the Pre-POINT study as a first step to potentially prevent type 1 diabetes in children that are at high risk for getting T1D," said Julia Greenstein, JDRF Vice President of Discovery Research. "This is a significant

finding and given JDRF's mission to achieve a world without type 1 diabetes, these study results are exciting and bring us one step closer to the potential of seeing an oral vaccination strategy to prevent this disease."

In follow-up studies, treatment will be given to a larger number of babies who are genetically at risk for type 1 [diabetes](#). If the vaccine then succeeds in preventing the disease over the longer term, this would open the door to blanket coverage with the preventive vaccine.

More information: Ezio Bonifacio, PhD; Anette-G. Ziegler, MD; Georgeanna Klingensmith, MD; Edith Schober, MD; Polly J. Bingley, MD; Marietta Rottenkolber, Dipl Stat; Anke Theil, PhD; Anne Eugster, PhD; Ramona Puff, PhD; Claudia Peplow, Dipl Eoc Troph; Florian Buettner, PhD; Karin Lange, PhD; Jörg Hasford, MD; Peter Achenbach, MD; for the Pre-POINT Study Group: Effects of High-Dose Oral Insulin on Immune Responses in Children at High Risk for Type 1 Diabetes. The Pre-POINT Randomized Clinical Trial. *JAMA*. 2015; 313(15):1-10. [DOI: 10.1001/jama.2015.2928](https://doi.org/10.1001/jama.2015.2928)

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