Modulating the natural history of type 1 diabetes in children at high genetic risk by mucosal insulin immunization.

Abstract:
Mucosal administration of insulin represents an attractive antigen-specific therapeutic approach to preventing type 1 diabetes. It can prevent autoimmune diabetes in animal models, but although it has been shown to be safe, it has not yet been proven effective in human studies. Efficacy may depend on the dose and route at which insulin is administered, the stage in type 1 diabetes pathogenesis at which treatment is initiated, and the study cohort that is treated. We have proposed Pre-POINT (Primary Oral/intranasal INsulin Trial), a dose-finding safety and immune efficacy pilot study for primary mucosal insulin therapy in islet autoantibody-negative children at high genetic risk for type 1 diabetes who naturally first develop autoimmunity to insulin. Pre-POINT aims to identify an optimal insulin dose and route of application (orally or intranasally) that is well tolerated and can induce an immune response to insulin for additional use in a phase II/III primary prevention trial in children at risk.

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