Primary dietary intervention study to reduce the risk of islet autoimmunity in children at increased risk for type 1 diabetes: the BABYDIET study.

To determine whether delaying the introduction of gluten in infants with a genetic risk of islet autoimmunity is feasible, safe, and may reduce the risk of type 1 diabetes-associated islet autoimmunity. A total of 150 infants with a first-degree family history of type 1 diabetes and a risk HLA genotype were randomly assigned to a first gluten exposure at age 6 months (control group) or 12 months (late-exposure group) and were followed 3 monthly until the age of 3 years and yearly thereafter for safety (for growth and autoantibodies to transglutaminase C [TGCAs]), islet autoantibodies to insulin, GAD, insulinoma-associated protein 2, and type 1 diabetes. Adherence to the dietary-intervention protocol was reported from 70% of families. During the first 3 years, weight and height were similar in children in the control and late-exposure groups, as was the probability of developing TGCAs (14 vs. 4%; P = 0.1). Eleven children in the control group and 13 children in the late-exposure group developed islet autoantibodies (3-year risk: 12 vs. 13%; P = 0.6). Seven children developed diabetes, including four in the late-exposure group. No significant differences were observed when children were analyzed as per protocol on the basis of the reported first gluten exposure of the children. Delaying gluten exposure until the age of 12 months is safe but does not substantially reduce the risk for islet autoimmunity in genetically at-risk
children.

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