

Hydrolyzed formula does not reduce diabetes-associated autoantibodies in at-risk infants

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Among infants at risk for type 1 diabetes, the use of a hydrolyzed formula (one that does not contain intact proteins) compared with a conventional formula did not reduce the incidence of diabetes-associated autoantibodies after 7 years of follow-up, according to a study in the June 11 issue of *JAMA*, a diabetes theme issue.

Type 1 diabetes is characterized by selective loss of insulin-producing beta cells in the pancreatic islets in genetically susceptible individuals. The disease process leading to clinical type 1 diabetes often starts during the first years of life. Some studies have suggested that exposure to complex foreign proteins in early infancy may increase the risk of beta-cell autoimmunity and type 1 diabetes in genetically susceptible individuals, indicating that prevention of the initiation of diabetes should start in infancy, according to background information in the article.

Mikael Knip, M.D., D.M.Sc., of the University of Helsinki, Finland, and colleagues randomly assigned infants at risk of [type 1 diabetes](#) to be weaned to an extensively hydrolyzed formula (n = 1,078) or a conventional cows' milk-based formula (n = 1,081). The dietary intervention period lasted until the infant was at least 6 months of age, and up to a maximum of 8 months of age, depending on the amount of exposure to formula (to ensure exposure for at least 60 days). The study was conducted at 78 centers in 15 countries. The primary measured outcome was positivity for at least 2 diabetes-associated autoantibodies out of 4 analyzed during a median observation period of 7 years.

During the follow-up period, 2,070 children (1,035 in each group) provided at least 1 blood sample for determination of [diabetes](#)-associated autoantibodies. The researchers found that 139 children in the experimental group (13.4 percent) tested positive for 2 or more [autoantibodies](#), as compared with 117 in the [control group](#) (11.3 percent). At least 1 autoantibody developed in 41.6 percent of those in the experimental group and in 40 percent of those in the control group.

The authors write that this study showed that in this large international trial, weaning to a highly hydrolyzed formula during infancy was not associated with any reduction in the signs of cumulative beta-cell autoimmunity. "These findings do not support a benefit from hydrolyzed formula."

More information: [DOI: 10.1001/jama.2014.5610](https://doi.org/10.1001/jama.2014.5610)

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