

## Dietary intervention can prevent the disease process leading to Type 1 diabetes

## November 10 2010

A Finnish study confirms the hypothesis that infant feeding plays a role in the initiation of the disease process leading to type 1 diabetes in children carrying increased genetic disease risk.

The study population comprised 230 newborn infants with at least one family member affected by type 1 diabetes and a predisposing genotype based on screening cord blood at birth. The participants were randomized into two groups; the infants in the intervention group were weaned to a highly hydrolyzed casein-based formula (Nutramigen, Mead Johnson Nutrition), while those in the control group were weaned to a regular cow's milk-based formula supplemented with 20% Nutramigen to make the two formulas comparable in terms of smell and taste. The intention was that the participants should be exposed to their study formula for at least 2 months by the age of 6 months, or if exclusively breast-fed up to that age by the age of 8 months.

The study participants were observed up to the age of 10 years for the appearance of diabetes-predictive <u>autoantibodies</u> and progression to type 1 diabetes. Twenty-five children (12%) developed at least two diabetes-predictive autoantibodies out of the five tested for, which marks a high risk of presenting with clinical diabetes. Seventeen children tested positive for two or more autoantibodies had been randomized to the control group (16%), whereas seven belonged to the intervention (casein hydrolysate) group (7%). Nine children (8%) in the control group presented with clinical diabetes by the age of 10 years, while four of those (4%) who had been exposed to the casein hydrolysate progressed



## to clinical disease

Professor Mikael Knip of the Hospital for Children and Adolescents, and University of Helsinki, who has been responsible for the analyses of diabetes-predictive autoantibodies states: "The study showed that the safe and simple dietary intervention applied in this pilot trial was capable of reducing the emergence of diabetes-predictive autoantibodies by about 50% by age 10 in the participants carrying increased disease risk. The current study population does not provide sufficient statistical power to definitely conclude whether an intervention of this type will reduce the frequency of clinical type 1 diabetes, although the preliminary data are promising."

A full-scale trial – TRIGR (Trial to Reduce IDDM in the Genetically at Risk) – was initiated in 2002 and is currently running in 77 study centers in 15 countries to provide a conclusive answer to the question of whether weaning to a highly hydrolyzed formula will reduce the cumulative incidence of clinical type 1 diabetes. A total of 2160 children have been randomized for TRIGR. The first end-point in TRIGR, i.e. positivity for at least two diabetes-associated autoantibodies and/or clinical type 1 diabetes by age 6, will be reached in 2013 and the final endpoint, clinical diabetes by the age of 10 in the year 2017.

The current pilot trial and the full-scale TRIGR aim at primary prevention of type 1 diabetes, i.e. to stop the initiation of the disease process which lasts for months and years before clinical disease manifestation. Dr. Knip emphasizes that the results indicate that it is possible to reduce the initiation of the disease process substantially by early dietary intervention in high-risk individuals. "On the other hand we have to keep in mind that this pilot trial has been performed in children with predisposing genes and a family member affected by type 1 diabetes. At this point it remains open whether this type of intervention will work in children from the general population," cautions Dr. Knip.



The researchers have not determined the decisive difference is between the casein hydrolysate and regular cow's milk-based formulas. An experimental study recently showed that a highly hydrolyzed formula reduces gut permeability and has a beneficial effect on gut microflora. Studies have been initiated to identify the mechanism(s) by which the highly hydrolyzed formula protects against beta-cell autoimmunity represented by diabetes-predictive autoantibodies.

Another Finnish trial is currently testing the hypothesis whether an insulin-free formula decreases the initiation of the diabetic disease process in children at risk given the central role of insulin as an early autoantigen in <u>type 1 diabetes</u>.

## Provided by University of Helsinki

Citation: Dietary intervention can prevent the disease process leading to Type 1 diabetes (2010, November 10) retrieved 25 April 2024 from <a href="https://medicalxpress.com/news/2010-11-dietary-intervention-disease-diabetes.html">https://medicalxpress.com/news/2010-11-dietary-intervention-disease-diabetes.html</a>

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