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Early feeding and risk of type 1 diabetes: experiences from the Trial to Reduce Insulin-dependent diabetes mellitus in the Genetically at Risk (TRIGR).

Knip M, Virtanen SM, Becker D, Dupré J, Krischer JP, Akerblom HK; for the TRIGR Study Group.

Hospital for Children and Adolescents, University of Helsinki, Helsinki, Finland and Tampere University Hospital Research Unit, Tampere University Hospital, Tampere, Finland; Nutrition Unit, National Institute for Health and Welfare, Helsinki, Finland.

Abstract

Short-term breastfeeding and early exposure to complex dietary proteins, such as cow milk proteins and cereals, or to fruit, berries, and roots have been implicated as risk factors for β cell autoimmunity, clinical type 1 diabetes, or both. The Trial to Reduce Insulin-dependent diabetes mellitus in the Genetically at Risk (TRIGR) is an international, randomized, double-blind, controlled intervention trial designed to answer the question of whether weaning to an extensively hydrolyzed formula in infancy will decrease the risk of type 1 diabetes later in childhood. In our pilot study, weaning to a highly hydrolyzed formula decreased by ≈50% the cumulative incidence of one or more diabetes-associated autoantibodies by a mean age of 4.7 y. This finding was confirmed in a recent follow-up analysis to 10 y of age. Currently, the full-scale TRIGR takes place in 77 centers in 15 countries. The TRIGR initially recruited 5606 newborn infants with a family member affected by type 1 diabetes and enrolled 2159 eligible subjects who carried a risk-conferring HLA genotype. All recruited mothers were encouraged to breastfeed. The intervention lasted for 6-8 mo with a minimum study formula exposure time of 2 mo, and hydrolyzed casein and standard cow milk-based weaning formulas were compared. Eighty percent of the participants were exposed to the study formula. The overall retention rate over the first 5 y was 87%, and protocol compliance was 94%. The randomization code will be opened when the last recruited child turns 10 y of age (ie, in 2017).

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