research news

TRIGR Study: A New Trial Investigates Environmental Triggers in Type 1 Diabetes

New York, NY, August 7, 2002 □ A large multinational study will be undertaken to assess the relationship of infant formula consumption to the likelihood of developing type 1, juvenile, diabetes in certain genetically at-risk infants. With a total budget of about $25 million, the study, called TRIGR (Trial to Reduce Insulin-Dependent Diabetes in the Genetically at Risk), is jointly funded by the National Institute of Child Health and Human Development (NICHD), the Canadian Institutes of Health Research (CIHR), the Juvenile Diabetes Research Foundation International (JDRF), the European Foundation for the Study of Diabetes (EFSD), Novo Nordisk, the Netherlands Diabetes Foundation (NDF) and the European Union.

The randomized, blinded, and controlled trial will compare the rates of development of type 1 diabetes in infants given hydrolyzed cow's milk based formula versus a standard cow's milk based formula. "Hydrolyzed" refers to the process of breaking down protein in cow's milk (such as casein) into smaller molecules. Some scientists have suggested that exposure to casein or other proteins in cow's milk formula or soy-based formula may play a role in triggering the immune system attack that destroys insulin-making cells.

Previous studies (in the U.S., Canada, Finland, New Zealand, and Australia) of whether early introduction of formula increases the likelihood of development of type 1 diabetes in humans have produced contradictory results; and as of now there is no compelling evidence to suggest that parents should change the dietary recommendations of their doctor, pediatrician, or nutritionist regarding consumption of cow's milk products. At the same time, the need for a larger, well-controlled scientific investigation has been called for to further explore the question, resolve the conflicting data, and further our knowledge about environmental factors that may increase the risk of diabetes in children who are susceptible. This study will be large enough to answer the questions about cow's milk products once and for all, says Duane Alexander, M.D., director of the NICHD.

The study recruitment will span 2 years and 14 countries-approximately 6,000 families with a history of type 1 diabetes and who are expecting a baby will be identified to participate in the study. A blood test will identify the newborns with the highest genetic disease risk. When the babies are weaned from breastfeeding, they will receive infant formulas that contain either no, or a reduced amount of intact foreign food proteins typically found in baby formulas. A control group will receive a standard cow's milk-based formula. Infants will have at least a two-month exposure to the study formulas and then will be monitored for up to ten years. Researchers will be looking for the appearance of antibodies to certain proteins of the insulin-producing cells of the body, signaling the beginning of the autoimmune process that destroys beta cells.

TRIGR involves over 40 centers across the U.S., Canada, Europe, and Australia. Dorothy Becker, MBBCh, chief of Endocrinology and Diabetes at Children's Hospital of Pittsburgh, heads the U.S. contingent, which was launched on June 10, 2002. Participating U.S. institutions are located in Los Angeles, New York City, Pittsburgh, Ponce (Puerto Rico), Seattle, and St. Louis.

Visit TRIGR for further information about the study and how to enroll.