

The project has received more than \$20 million from the National Institute of Child Health and Human Development and support from a variety of diabetes organizations, pharmaceutical companies and governmental agencies.

Along with Children's Hospital, the American study centers are Columbia University in New York City, Washington University in St. Louis, the University of Washington in Seattle, the University of California at Los Angeles, and Ponce University in Puerto Rico.

Babies who have a parent or sibling with Type I diabetes could be eligible for the trial.

Scientists theorize that because an infant's gut is immature, large proteins leak through pores that normally shrink with age. These complex proteins may trigger the formation of antibodies against insulin-producing cells.

In laboratory experiments, use of hydrolyzed cow's milk formula reduced the incidence of diabetes by as much as 90 percent in rats and mice prone to the disease.

The hydrolyzed formula has been used for many years by children who have certain allergies or gastrointestinal conditions. It costs several times more than traditional formula.

If it does prevent diabetes, Becker added, "it'll cause a revolution in the baby milk formula industry."

Researchers are not suggesting any changes from recommended feeding guidelines, and mothers in the study will be encouraged to breast feed. But any formula that is given must be supplied by the study organizers and neither the researchers nor the parents will know which kind it is.

The babies will be tested every three months until age 1, at 18 months and at 2 years, and then annually until at least age 5 and likely to age 10. Of the 2,400 high-risk children to be enrolled, researchers normally would expect between 240 and 360 to develop diabetes.

Individuals who have Type I diabetes or a spouse or child with the disease and are expecting a baby can learn more about the trial by calling Margaret Franciscus at 412-692-5250.

Children's a trial site for diabetes prevention

By Anita Srikameswaran
Post-Gazette Staff Writer

A baby formula that has the potential to prevent Type I diabetes in high-risk infants is going on trial worldwide and a Children's Hospital expert is heading the American arm of the study.

Dr. Dorothy Becker, the hospital's chief of endocrinology and diabetes, will collaborate with researchers from London, Ontario, to lead all the North American centers in the 10-year Trial to Reduce Insulin-Dependent Diabetes in the Genetically at Risk, or TRIGR.

The study will address a theory that infants fed formulas based on soy or cow's milk may be at greater risk for diabetes. Scientists aren't sure how this might take place, but suspect that something about the complex proteins in those formulas confuses a baby's immune system and causes it to attack and kill insulin-producing cells.

In the study, about 2,400 babies who have a parent or sibling with diabetes will be fed either regular baby formula or a formula that has been processed to break down complex milk proteins. As they get older, the children will be regularly monitored for signs of the disease. The first two American babies, both from New York, began the study last week, Becker said.

The trial is designed to intervene before babies develop the antibodies that destroy the insulin-secreting cells in the pancreas, which causes Type I diabetes.

"TRIGR is the first and only primary prevention [study]," Becker said. "That is, [it tries] to prevent the inflammatory process from starting in the first place."